CENTERS FOR MEDICARE AND MEDICAID SERVICES

PRACTICING PHYSICIANS ADVISORY COUNCIL

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Room 505A
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Public Witnesses

Dr. Ardis D. Hoven, American Medical Association
Dr. Albert Bothe, Association of American Medical Colleges

MS. DANA TREVAS, Rapporteur

A G E N D A

Morning

Afternoon

Open Meeting

Dr. Castellanos: Good morning. I would like to try to start the meeting on time and see if we can stay on schedule. As you can see, we have a very busy program this morning. Again, good morning. I'm Dr. Ronald Castellanos, Chairman of the Practicing Physicians Advisory Council, and it's my pleasure to welcome you on the occasion of the 53rd Council meeting. I'd like to extend my cordial welcome to my colleagues and fellow Council members. I appreciate your willingness to travel here to Washington and to participate in this very important meeting. Your considered input and guidance on the various issues that will be presented here today significantly influences the outcome of the regulations and instructions which directly affect the physician community. As we look at today's agenda, you'll see that there are several issues being presented today for our consideration. These topics include the Surgical Care Improvement Partnership Program, the National Provider Identifier Outreach and Implementation, the Part D Prescription Drug Program, the Competitive Acquisition Program, the Physician Fee Schedule and Outpatient Proposed Rules, and the Alliance for Cardiac Care Excellence Program. We'll also have a presentation by PRIT. And we're also going to get the responses to our May 23, 2005 PPAC meeting. I'm confident that you'll give our presenters the full benefit or our practical knowledge and insight. I'm anxious to get started with the agenda we have before us today, but before we begin, there is a brief announcement. CMS would like all of us to know that they've recently updated the PPAC website. This update will allow each of us to access pertinent PPAC information and documents in response to the various questions raised throughout the quarter. The PPAC update is available on www.CMS.HHS.GOV/FACA/PPAC. Now I'd like to thank all of you for being here today. We look forward to a very productive meeting and discussion on the issues relative to the various Medicare Program areas. These are very exciting and challenging times in addressing these issues in our health care delivery system. It's now my pleasure to introduce Dr. Tom Gustafson, Deputy Director of the Center for Medicare Management, Centers for Medicare and Medicaid Services to welcome you.

Welcome

Dr. Gustafson: Thank you, Dr. Castellanos. I'm Tom Gustafson. I'd like to extend my welcome to the Council and to the many guests here in the audience. And I'll be here with you all day, but want to let you know that Herb Kuhn, my boss, is tied up in an airport someplace. He was intending to be here this

morning, but the forces of nature did not cooperate. And the Fee for Service Program is alive and well and continuing to do its many things. Our center issued six regulations within a week of August 1st, this year. You'll hear about two of them later today. The Physician and Outpatient Proposed Rules, but we issued Final Rules in the Part A Sector of the Program, so even as the Agency is gearing up for the Part D Prescription Drug benefit, and for a number of other initiatives, some of which you will hear about today, we're back in back in Baltimore, continuing to attend to business not quite as usual, but business with a great deal of overlay of new stuff coming along. I really don't have too much to say that wouldn't have been obvious to you before you got here. Very glad to have you here. This Council has served the Agency very well over the years, provides an important listening post for us in terms of understanding what is going on in the practicing physician community, and we very much look forward to today's deliberations. Having said that, I yield back the balance of my time, Mr. Chairman.

Dr. Castellanos: Thank you, Dr. Gustafson. It's my privilege at this time to introduce Dr. Ken Simon, the Executive Director of the Practicing Physicians Advisory Council, Center for Medicare Management. He'll provide us with the update on the May 23rd 2005 Recommendations of our Council, and the Centers for Medicare and Medicaid services's response.

Update

Dr. Simon: Good morning, Dr. Castellanos, Council members, and the public. I'll discuss the recommendations that were obtained and given to us by the Council from the May 23rd meeting.

Agenda Item C-1, PPAC recommends that CMS issue an interim Final Rule to allow more time for public comments about Competitive Acquisition Program. The Agency has accepted the Council's recommendation and published an interim Final Rule on the Competitive Acquisition Program on July 6, 2005 and we will continue to accept public comments until September 6, 2005.

Agenda Item C-2, PPAC recommends that CMS develop a plan to monitor critical subsets as possible indicators of barriers to access to care, such as new versus established Medicare patients, patients without Medigap coverage, and specialty versus primary care physicians and that CMS develop a plan to address possible declines in access before problems become widespread. CMS is required to report to Congress by July 1, 2008, about the CAP implementation. In that report, CMS plans to evaluate the impact CAP has had on access to care, beneficiary satisfaction, and other issues. CMS conducts and monitors

environmental scanning through ongoing quarterly meetings with the regional offices to ensure an early warning alert in the event trends emerge that could indicate significant changes.

Agenda Item D-1. PPAC requests that PRIT provide more detailed information at the Council's August meeting on issues of carriers reimbursing evaluation and management claims at half levels. Further, PPAC recommends that CMS and its carriers use the existing documentation guidelines to determine payment levels, rather than arbitrarily assigning other payment levels. CMS response: The use of CPT-Code 99499, which is an unlisted evaluation and management code, can be used when physician documentation is inadequate to support using any of the existing CPT-Code evaluation and management codes. The use of this code has created unanticipated problems with the calculation of the certification error rate, and this issue has been reviewed by the Program Integrity Group within CMS. The Agency recognizes that there may be the occasional circumstance when a clinical service provided to a beneficiary doesn't reach the threshold of a low-level new patient visit, i.e., CPT-Code 99201, or an established patient visit, CPT-Code 99211 at which time the 99499 code should be used to describe the service provided. The carriers would determine the appropriate payment for those services when rendered. Any service that reaches or surpasses the 99201 or 99211 threshold would have the usual coding guidelines apply. The infrequency of the use of 99499 would result in such low volume usage of the code that it should not create problems with calculating a cert. error rate.

Agenda Item D-2. PPAC requests that PRIT provide the Council with the list it has compiled of drugs that physicians feel are difficult to purchase under the average sales price methodology. The Agency has submitted to the Council members, the drug names, the drug prices, as reported by practitioners and the best prices we have been able to find to the CMS staff responsible for maintaining the ASP list. The CMS staff has in turn contacted the manufacturers as well as local carriers and providers to verify that the calculations and the data that the manufacturers have used to calculate the ASP in question are correct and to also determine whether there have been any problems by the providers with obtaining pricing or drugs through the ASP list. And so those questions that have been raised by the medical community to the CMS staff have been addressed and resolve.

D-3. PPAC requests that PRIT evaluate the proposed rule for hospital Conditions of Participation and seek to exclude non-emergency department visits from the requirement to use time stamps. We are

currently discussing the recommendation with practitioners and attorneys. There is a general feeling, however, that writing a time when a note or order requires no additional effort and is a good habit to develop. We will continue to invite comments as we try to develop a sense of the general opinion of the provider community.

Agenda Item F-1. This pertains to the Recovery Audit Contractors, or the RAC Program. PPAC recommends that the evaluation of the RAC demonstration project weigh the cost of administration of the project by the RACs. CMS and providers and physicians against the amount of money recouped by the RACs in overpayment. CMS agrees that evaluation of the RAC demonstration should include a number of factors, including CMS administrative costs, the affect of the demonstration on the provider community, including provider administration costs and the net impact for the Medicare Trust Fund. Additionally, the evaluation includes an analysis of the cost incurred by the RACs themselves and will compare the RAC operations to historical Medicare operations.

F-2. PPAC recommends that if a physician or provider successfully appeals a claim determination made by a RAC, the RAC must reimburse the physician or provider for expenses incurred by the appeal. The response: Financial negotiations with potential bidders concluded in March, and contracts were awarded based on a specific statement of work that did not include this requirement. Therefore, CMS is precluded from making this change without renegotiating the RAC contracts and contingency fees. CMS believes it is not in the best interest of the program to enter into a renegotiation process at this time. However, CMS will consider this recommendation in the future.

Agenda Item F-3. PPAC recommends that issues related to teaching physician guidelines be excluded from the RAC purview for claims determination. The response: CMS designed the demonstration to closely mirror the current Medicare environment. The RACs must follow all national and local guidelines regarding coverage and payment policies. Therefore, CMS included services provided by teaching physicians.

Agenda Item F-4. PPAC recommends that CMS and the RACs notify the provider community of each new area of review, such as review of outpatient claims. CMS agrees with the recommendation, and to the extent possible, CMS will notify provider communities of new focus areas before the RAC requests

medical records or transmits overpayment demand letters. Notification may be via CMS channels of communication, such as the MedLearn articles, or through the state associations.

F-5. PPAC recommends that when CMS reviews the RAC performance, CMS ensures that underpayment issues are evaluated and reported appropriately. CMS agrees with this recommendation. The RACs report potential overpayments to CMS monthly. Additionally, the evaluation of the RAC demonstration incorporates determined underpayments and the identification methodology.

Agenda Item D pertaining to the National Provider Identifier Update. The first recommendation: The Council recommends that CMS develop an NPI directory that would be appropriately accessible to provider for the purposes of claims submission, and that the directory include appropriate security measures to protect the data. CMS agrees in principle but needs to determine the HIPAA security requirements. The Agency plans to publish 606-N Date of Dissemination Notice, in the *Federal Register* in October, of this year. This notice will provide the details addressing the procedures that providers and other entities must follow in order to obtain information from the National Plan and Provider enumeration system. Called the NPPES system. Our notice must balance the need for covered entities to obtain NPI data for use in HIPAA standard transactions against Privacy Act and security requirements. We are aware that in order to complete standard transactions, some providers will need to utilize and thus have some access to the NPI of a referring provider. We are currently looking at the possibility of publication of an NPI registry made available to the public. However, unlike the UPIN, the NPIs are the actual billing numbers to be used by all health care providers for all healthcare plans and unlimited access to these numbers by the general public could create a significant program vulnerability. Should CMS decide that the publication of an NPI registry is not compatible with security requirements and/or the Privacy Act, we will ensure that CMS 6060-N provides a methodology for providers to obtain these numbers as required.

Agenda Item G-2. PPAC recommends that CMS clarify exactly which identifying numbers will be eliminated or replaced by NPIs and which entities needs their own NPIs, such as group practices, independent physician associations etc. CMS agrees in principle. The implementation guides for the standard transactions are the authoritative source for determining the situations in which health care providers must be identified in standard transactions. Generally, by the May 23, 2007 compliance date, where a standard transaction requires the identification of a health care provider as such, the NPI will be

used in place of the Legacy Provider Identification. Specifically, as of May 23, 2007, the following current identification numbers will not be used in the standard transactions: PIN, Provider Identity Number, the National Supplier Clearinghouse, Online Survey & Certification and Retrieval System, the Unique Physician Identification Number, and the National Council for Prescription Drug Program. The NPI will replace these previously assigned numbers in all standard transactions, though health plans may continue to use current numbers internally. The NPI of the individual referring or rendering physician/practitioner will be used as the billing number. Frequently, a number of providers are identified on a particular claim, especially with regard to institutional providers. For example, in the case of a radiology group, the radiologist who perform the procedure would be the rendering physician and therefore use his/her NPI. The radiology group itself would likely maintain a separate NPI and that number may appear on the standard transaction as the billing provider. Further, an alternate provider may be designated for payment, so its NPI would be part of the transaction as well. Any health care provider who submits standard transactions must apply for and receive an NPI. The Medicare Health Plan is developing a guideline document which details how the Medicare Program envisions the NPI enumeration of its enrolled providers based on the information in the NPI Final Rule. We expect to make this document public shortly.

Agenda Item J pertaining to Part D Prescription Drug Program. The Council recommends that at the August 2005 PPAC meeting, CMS provide the Council with an update on its efforts to make beneficiaries aware of the new benefit, supply samples of educational materials for beneficiaries and providers, and give detailed information on the formularies to be used. CMS agrees with the recommendation by the Council and forwarded to all of the PPAC Council members the tool kit for the Part D benefit. An update on our outreach and transition efforts will be reported at the meeting today. And information concerning the formularies cannot be released before the prescription drug plans post them.

Agenda Item K, pertaining the Competitive Acquisition for Drugs. K-1, the PPAC reiterates the recommendations made at its March 7, 2005 meeting. 51-F-1, PPAC recommends that CMS require vendors, selected through the CAP program to absorb the cost of returned drugs, or of unusual drugs and that vendors be willing to advance credit for drugs to patients who are not able to pay the co-pay. CMS agrees with the PPAC recommendation. And we outlined in the interim Final Rule that vendors will be responsible for the cost of returning unused drugs to them. We have worked with the Office of the

Inspector General to craft a policy that allows vendors to provide assistance to beneficiaries, who cannot make the co-insurance payments for their drugs. In addition, vendors cannot collect the co-insurance from a beneficiary until the vendor has confirmation that the drug has been administered.

51-F-2. The Council recommends that CMS require vendors selected through the CAP, be willing to provide drugs for off-label use when evidence supports such use. In such cases, vendors may use the established CMS process for determining medical necessity. CMS agrees with this recommendation. All local and national coverage determinations will continue to be in place under CAP. This will allow physicians to continue to provide drugs for off-label use as long as it is consistent with any existing and relevant LCD or NCD.

51-F-3. PPAC recommends that CMS allow individual practicing physician to select on a drug by drug basis whether to purchase drugs from vendors participating in the CAP program. CMS appreciates the Council's comment, but in order to participate in CAP, vendors are required to offer the full list of drugs in the CAP category, and physicians are required to make the decision to participate in CAP for the entire category of drugs rather than a drug by drug basis.

51-F-4. The Council recommends to CMS that prices set by vendors selected through the CAP process not affect the averages sales price for those who purchase drugs outside of the CAP program. CMS is sensitive to the potential for CAP prices to affect the average sales price, however, the Agency does not have the legal authority to remove the CAP sales from the calculation of the average sales price.

51-F-5. PPAC recommends that CMS help affected providers find sources of affordable drugs, and that CMS report to PPAC some mechanism to accomplish this goal, which was recommended by the Office of the Inspector General. The CAP Program will provide physicians with an alternative to the ASP-based system, in which physicians must buy the drugs individually and then bill Medicare for them. Under CAP, physicians will order drugs from approved vendor, and the vendor will be responsible for acquiring the drug and billing Medicare. In addition, as CMS designated the CAP drug list, we were sensitive to the concerns we have heard about particular drugs physicians have had difficult acquiring under the ASP system, and we have made an effort to include these drugs in the CAP Program.

K-2. PPAC recommends that CAP be fully implemented for all specialties and all drugs without limited formularies regardless of a patient's ability to pay a co-pay and with no additional administrative

duties or costs to the physician. CMS agrees with the recommendation. The first round of CAP will take place in one nationwide geographic acquisition area, with one category of drugs that encompasses all specialties of physicians. Although we did not include all Medicare Part B drugs in the first round of CAP, because certain drugs were very low volume, or posed other operational challenges, the 181 drugs included in the CAP comprised over 85% of Medicare spending on physician injectable drugs. There are no formularies in the CAP, and we encourage vendors to assist beneficiaries with co-insurance payments consistent with the Office of the Inspector General's guidelines.

K-3. PPAC recommends that CMS stipulate that CAP vendors not be allowed to market directly to patients, or to sell physician prescribing data to pharmaceutical companies or anyone else without the physician consent. CMS response: An approved CAP vendor is a HIPAA-covered entity, and is subject to the HIPAA Privacy Rule that governs the use and disclosure of protected health information.

K-4. PPAC recommends that physicians be allowed 30 days for a submission of verification of administration. CMS understands PPAC's concern about billing timeframes, but the Final Rule requires CAP participating physicians to submit a CAP claim within 14 days. Our claims data suggests that this is consistent with the practice patterns of most physicians.

K-5. PPAC recommends that the process of prescription submission and claims submission require only limited essential data on the basis of the recommendation of specialty societies. CMS agrees with the CAP order form and claim and will require only information that is essential to filling the order and paying the claim. In addition, once a CAP patient is established with a vendor, subsequent CAP orders will require a more limited set of information. We encourage specialty societies to submit comments to the Interim Final Rule on data elements. We carefully considered the data included in the drug orders as finalized in the interim Final Rule. The required data elements may change as our experience with CAP grows.

Agenda Item K-6. PPAC recommends that the definition of emergency include patient hardship and rescheduling office visits due to a delay in delivery and therapy. CMS does not agree. The interim Final Rule defines emergency as an unforeseen situation determined by a physician in his or her clinical judgment to require prompt action on the part of the physician to supply the patient with drugs from his or her own stock. The situation also must comply with the other three criteria specified in the statute, i.e., the

drugs were immediately required, the physician could not have anticipated the need for the drugs, and the vendor could not have delivered the drugs in a timely manner.

Agenda Item M. Pay for Performance Initiatives, quality measures. 52-1 PPAC recommends that CMS support legislation or otherwise devise a system that allows the transfer of money saved from Part A into Part B when savings occur as a result of better outpatient management, that results in fewer complications, less hospitalization, or less use of the emergency department. CMS recognizes the concern and appreciates the potential impact on clinicians. A statutory change however would be necessary. And we would consider the possibility of supporting such a change.

52-2. PPAC recommends that CMS describe the current methodology proposed to allocate dollars saved from the improved performance to providers. CMS acknowledges the question, but there is no current methodology proposed for the allocation of dollars, as there is not a national Pay for Performance Program at this time.

This entails all of the recommendations, Dr. Castellanos, that the Council recommended to the Agency from the May 23rd meeting.

Dr. Castellanos: Thank you Dr. Simon. Are there any further questions or comments from the Council members? Dr. McAneny?

Dr. McAneny: Yes, on C-2. The intent of C-2 was not to be strictly on the CAP program, but was more in relationship to the Physician Fee Schedule than the decrease.

Dr. Simon: C-2?

Dr. McAneny: C-2. It's put in under discussions with CAP. But from our discussions, last time the intention there was our concern that with the Physician Fee Schedule change, that certain specialties or certain areas of the country perhaps more rural or frontier type areas, or certain specialties with decreasing numbers of availability would be the canaries in the mind that would signal an early warning for access to case. It wasn't really just talking about CAP, it was really intended to talk about the entire Physician Fee Schedule, but the reply seems to reflect just the CAP program.

Dr. Simon: OK. I'm not sure what the appropriate response is. The response addresses the question, or the recommendation as it was posed by the Council.

Dr. Gustafson: Let me jump in here, Ken, as far as I can help you out. We apologize if there was some confusion about the intent of the Council in this area. And without having detailed specifics right at my fingertips, although, I believe Amy Bassano is on the agenda later today may be able to provide some further detail. We are engaged already in monitoring of the possible problems relating to drug use by various specialties and how the introduction of the new ASP system—you're shaking your head.

Dr. McAneny: It wasn't to do with drugs. Our recommendation came under discussions of the Physician Fee Schedule. That we were looking at the impending 26% decrease in Physician Fee Schedule on physician participation in Medicare. And we were concerned about Medicare patients' access in general. Not just to drugs at all.

Dr. Gustafson: Oh yes, I now take your point. And again, without a vast detail right at my fingertips, we have a set of activities we've been engaged in examining the problems, or potential problems with access in various areas of the country or with various specialties, primarily I believe through the Office of Research, Demonstrations, and Information. This is something that we expect to continue and expand our attention to because obviously the size of the suggested reductions over the next several years is worrisome to us all. Our mission continues to be able to provide high quality care, to facilitate the provision of high quality care to all of our beneficiaries, in so far as access problems would arise, we need very much to be aware of them. There is a problem in this area of discerning what's actually going on as opposed to what people are saying is going on that we all need to be aware of. And we're attempting to monitor that situation closely.

Dr. Castellanos: Are there any other questions, or comments? Dr. Grimm?

Dr. Grimm: Yes, I have a question about this is regarding the PPAC recommendation that CMS review the RACs performances. And it says that you mentioned that CMS agreed that the RACs report potential underpayments to CMS. Is that same information available to the provider?

Dr. Simon: That information should be public information. I will report back to the Council at the next meeting how that information would be disseminated back to the individual provider.

Dr. Grimm: Does the RAC get rewarded for finding underpayment?

Dr. Gustafson: I think we're going to have to consult with the RAC management to explore the details on this.

Dr. Grimm: I suspect they're not. So there's not a lot of incentive for them to report underpayment.

Dr. Castellanos: As it was presented to the Council, their salary's definitely just determinate on percentage of over, not under.

Dr. Grimm: Is that right?

Dr. Castellanos: They're required to provide that information, but there's nothing presented to us as far as any reimbursement to them for providing that information. Could we find out some additional information?

Dr. Simon: I could follow up and present that back to the Council at the next meeting.

Dr. Castellanos: And whether it's going to back to the individual or just to CMS, that's—

Dr. Simon: Back to the individual as well as the methodology that will be used to make the information available to the individual.

Dr. Castellanos: Are there any other comments? Dr. Sprang?

Dr. Sprang: On K-4, PPAC had recommended physicians be allowed 30 days for submission verification. In general, I think, in allowing 30 days for billing in almost any area, is just much more reasonable. And in Illinois, some of the 3rd party carriers tried to make it a 14-day change in the state [inaudible] worked very vigorously to get it changed to 30 days. Just in small offices, in many offices, they're just not going to be able to do a turnaround in 14 days. I think most across the board 30 days would be a much more reasonable time frame for billing for anything, and so I'd I think, we should ask them to look at this again. And 30 days are just much more reasonable. 14 days for some offices would actually be onerous.

Dr. Castellanos: Do you want to make that as a recommendation at this time?

Dr. Sprang: Yes, I would recommend that CMS look at this request again and try to come back with more suitable answer. [laughter]

Dr. Castellanos: Just a comment to CMS on that. I think as Ken, as you said, as the majority of people probably can do it within 14 days, and large practices no question have that ability. But I think the small, one- and two-man practices can't do that. And also if you look at CMS, this is the only regulation

where there's a time limit. Most of the time it's up to a year they have to provide, to put in a claim. So it's a little unusual that CMS would require that. But I can certainly understand why you want to do that.

Dr. Gustafson: A couple of quick points here. First is the comment period on this regulation is still open, so that folks certainly have an opportunity to call this issue to our attention and I'm sure many people will be doing so. So we have not arrived at a final position by virtue of the situation we're in. We in fact have suspended the bidding program precisely to allow better opportunity for the opinions of the community to be voiced to us and for us to take those into consideration. We were on a timeline which was going to move somewhat more aggressively, we are now moving somewhat more slowly in order to do this in a more deliberate fashion. So this is an issue we definitely will be looking at further. We will welcome the Council's recommendation on that subject. I think it only reasonable to note here that the construction of the CAP program in general is a somewhat difficult balancing act for the Agency. Obviously, this needs to work from the standpoint of the individual physician and their procedures within their offices. It also needs to work from the standpoint of the potential bidders, the potential vendors of care. And to be blunt about it, neither party is likely to get everything they want out of this in order to try to have a balance that will make it workable. That having been said, we will of course we watching closely as this thing proceeds, and there will be opportunities for further adjustment as we all gain experience with this. We haven't done this kind of thing before. We're breaking new ground here, and that in itself is a little bit of an awesome responsibility.

Dr. Castellanos: I think there's a motion on the floor. Could you repeat that for us?

Ms. Trevas: The Panel recommends that CMS again review the recommendation that physicians be allowed 30 days for submission of their application of administration.

Dr. Castellanos: Is there any further discussion? I'll call the question. All in favor?

[Ayes]

Dr. Castellanos: Opposed?

Dr. Simon: In recognizing that the comment period closes September 16th, the recommendation as well as the comments pertain will be considered as part of the information during the comment period as well.

Dr. Castellanos: Are there any other comments? Yes, Dr. Sprang?

Dr. Sprang: So for the 52.1. PPAC recommends CMS support legislation or otherwise devise a system that allows the transfer of monies saved from Part A into Part B where savings occur as a result of better care. Obviously, in general, I think everybody knows hospitals are a very expensive place to provide care, so anything that physicians can do to limit care in the hospitals, through better care, or whether it's doing some minor office procedures, clearly I think it's the advantage of CMS and health care in general better use of dollars. I think the issue is important enough and obviously it's where I think Pay for Performance is going etc., to try to do something in a more efficient, cost-effective process. I think it's a major issue. It would significantly maybe decrease costs for CMS and have just more cost-effective medicine. And so it says CMS recognizes the concern, appreciates the potential impact on clinicians. A statutory change would be necessary and we would consider the possibility of supporting such a change, so I guess I would take it further and take what you're saying, you would consider supporting such a change, and actually encourage you to try to create such a change.

Dr. Gustafson: Perhaps it would be well to jump in here and explain the development process for statutory changes. The Agency proposes changes to the President through a process managed by the Office of Management and Budget. That is an internal deliberative process, and this is reviewed as part of the construction of part of the annual budget, and should we say, many factors come to bear in that in terms of what the President wishes to advance to Congress as a program. So you will see in this and other recommendations or our response to other recommendation, a certain caution relative to statutory changes simply because we are not in a position to say, yes, we will support that, because if the President says no, you won't, then we don't. So the construction you see here on the page was carefully crafted in order to indicate our receptivity toward the general point, we think that it's—we would have to be dumb not to notice that what physicians do controls a lot of what goes on in hospitals and other sectors of the health care industry, and we'd like to find ways where increased efficiencies there and improved quality can be appropriately recognized, not just for the hospital, but also for the physician. How we get there is a little bit intricate.

Dr. Sprang: I think all I was trying to do is emphasize that I really think this is an important issue, and has a lot of potential for saving money and giving people incentives to go in the right direction is obviously always a good thing. That's really what I was trying to do, just shine a little brighter light on that.

Dr. Simon: Thank you.

Dr. Castellanos: Are there any other comments? Dr. McAneny?

Dr. McAneny: I appreciate Dr. Simon's telling us that he'll get back to us on the RAC system and find out what has happened, particularly whether there is any underpayments found. But I would like to hear at the next meeting also a lot more detail about what has been investigated, whether or not the reports are reported also back to the carrier. I am bothered by the idea that if they find an underpayment or an overpayment that that becomes public knowledge. It seems to me it might be more appropriate to have the information be transmitted back to the physician who had the underpayment or overpayment and to the carrier and so I would like to recommend that CMS share with PPAC at the next meeting an update on the Recovery Audit Contractor Program and its efficacy.

Dr. Castellanos: Would you please repeat that?

Ms. Trevas: The Council recommends that CMS share with PPAC at PPAC's next meeting an update on the Recovery Audit Contractors and its efficacy.

Dr. Castellanos: And report it back at the next meeting. Is there any other comments on that? Any discussion? All in favor?

[Ayes]

Dr. Castellanos: Opposed? Are there any other comments concerning Dr. Simon's presentation? Dr. Simon thank you very much, we appreciate your comments, as usual. Part D Prescription Drug Program. We're certainly interested in hearing what our next speaker has to share regarding the Part D Prescription Drug Program. You're not going to find a copy of the PowerPoint presentation in our binder, however, Dr. Jeffrey Kelman, Medical Officer in the Center for Beneficiary Choices and the Centers for Medicare and Medicaid Services, is prepared to advise us on the progress of this exciting and innovative program. Dr. Kelman, we welcome you back, and we thank you for taking time out of your busy schedule to address our Council.

Part D Prescription Drug Program

Dr. Kelman: Thanks for having me back. I wanted to first give you an update on where the program is, then talk about the active areas, and last, there are some questions that I'd like help with from this group. Did you all get the information that I sent out about the Part D?

Dr. Castellanos: Yes.

Dr. Kelman: Good. I'm always afraid that whatever effort, I make, nothing actually goes to the recipients and it's nice to know that it arrived. [laughter] Well, since we last talked, we've had a very robust response from the plans. There will be a very full benefit in all 34 regions. There will be a lot of plans, many choices, and many choices for low income, non low income full benefit duels. Two weeks ago, we published the National Benchmark, which means we know what the premium is. It is $33.30. This is a lower premium than we expected, and part of it is a testimony to the robustness of the response. That's the average premium nationally. There'll be some lower, some higher, and if you're a member, found in the toolkit, there are 34 regional average premiums, and plans at or below that premium will be the ones available for full benefit duels, of the low income subsidy. By now I've seen all the formularies, have been submitted. And the formularies are much more robust than we expected. There was a lot of publicity about 8, 9 months ago about the USP guidelines. Well, it turns out that the USP guidelines are very useful. But they're more of a structure, they're a floor, not a ceiling. All the plans have gone way beyond the USP guidelines in a certain extent. We have 6 classes of special concern, the anti-psychotics, anti-depressants, anti-convulsives, which have a lot of the mood stabilizers, the chemo-therapy drugs, the antiretroviral drugs, and immunosuppressants, in which all are substantially, all products have to be on all the formularies. There are 100 key drug types, 100 common drugs, and a very strong requirement against discrimination. As a result, the PDD formularies we've seen are in general much more robust than all the state PDLs for the state Medicaid Agency, and in fact more robust than most commercial formularies we've seen. That's going to make the transition starting in January much easier. But beyond that, all the plans have confirmed with our transition requirements for time to transition people to the new formularies, although the need of transition will be lower than expected because the formularies are so broad. We're developing a new web tool, and this gets important for practitioners that will allow the beneficiary and the physician to identify the plans they have been auto-enrolled into or have actively enrolled into with

information on the Medicare card. Name, date, and birth, HIC number, effective date of Medicare, and probably Zip code. There was a big question last time we spoke about how people are going to know what plan they had been auto enrolled in for the full benefit duals. Now, they can do it on the web, or more likely, their physician, pharmacists, social worker can do it on the web. The key dates, and there are a couple of key dates, and now that all the applications are in, we know what they are. The low income subsidy can be applied for now. And that's very important because as opposed to the 6.5 million full benefit duals, who are auto-enrolled and deemed into the program, the 7.5 or 8 million low income subsidy people between 100 and 150% of federal poverty have to make an affirmative decision to apply for the benefit or they don't get it. Once they apply, it lasts for the year and for most cases, it'll be permanent. They need to enroll in a plan but if they don't, they'll be facilitated enrollment, but not till May. Applying for this application though is important. And presumably physicians are going to be asked about it. There was a Kaiser pole, fairly recently, that asked seniors who they were going to go to for information about the Part D plan. Physicians were way on top, followed by pharmacists, Social Security Administration, friends and family, Medicare, then senior centers. For the low income subsidy, it can be applied to through Social Security, through a mailed application, through a 1800 number to be the mailed application, or most simply on line. At www.SSA.GOV under New Medicare Drug Plan, the application can be produced, either printed out or filled out on line with edits and it's done. It's actually, for Social Security, it's a very simply application, having done some of the test studies, watching people fill it out. It can be done by a beneficiary, as opposed to many things which need direct help. But if they don't fill it out, the benefit just isn't there. In October 1st, marketing can start. Plans are expected to send people notes. There will be TV ads, subway ads, direct ads. October 15th, the auto-enrollment will start and so Medicaid, Medicare dual eligibles should be getting letters at that time, telling them which plan they've been auto-enrolled into. They can change plans on a monthly basis if they like in this group, but if they don't, that's the plan that will start January 1st and that's the plan that will be identified by the web tool. On November 15th, enrollment is open to everybody else, and the open season goes beyond January 1st, but we'd like everybody who is going to enroll to enroll if possible before January 1st when the benefit starts.

There are a few active areas which we're spending a lot of our time on now. And they're clearly education, communication, and enrollment. In terms of the low income subsidy, Social Security mail, a lot

of applications around the country. We're holding events to try to get people to enroll. We'll doing mail order. There are going to be ads. There is institutional questions. Most notably, the nursing home. This was always the most difficult part to get into the program, because a nursing home resident doesn't have the choice to go to a network pharmacy. And it's not practical to get it by mail in most cases. The structure that was established was to require the PDPs to meet certain performance and service criteria. For nursing home residents, specifically, they can do it through the existing long-term care pharmacies, or through new vendors. When their networks are established, the individual nursing homes have the right to choose which vendors supply all their residents. In theory, with a broad enough network, the nursing homes can stay in the one-vendor, one-nursing home, because the vendors who want to be active in this area will have signed up with all the plans. It seems to be working that way, but it involves a certain amount of negotiation between the plans and the vendors. For the nursing homes, it's critical that by end of October, they know exactly which plans their residents are in, so in November and December, if necessary, they can shift patients to the correct drugs before January 1st. I think the last thing everybody wants is all drugs being changed on all pharmacies for all residents, January 1. I mean it's just not practical. On the other hand, the formularies are now very robust. I mean there turns out to only be certain ways of writing formularies to meet our requirements, so there is going to be a need for much less shifting that some people expected. There is also the question of state mental hospitals, the ICFs/MR also have to be brought into the program, but in terms of the ICFs/MR, they generally use point of sale pharmacy. State mental hospitals, we're trying to get their dedicated pharmacies are part of the programs in their long-term care. And then there is the last special group, employer groups. For November 15th, people who have employer drug coverage, should be getting a letter from their employer stating whether it is as good or better than the Part D benefit, and what the employer recommends. The employer can continue the coverage, they can have a special PDP based on the employer they can contract out with a sponsor. In most cases, people with employer drug coverage will have to do nothing. Make no changes and continue the coverage they have. There are cases where they'll have to change, or may want to change to a Part D plan.

The questions that are coming up are really those of outreach. It's very clear that the practicing physician will be the point of contact for patients asking about the benefits, wanting to know what to do. And we're not quite sure the best way of reaching physicians—I mean, is it toolkits? Communications, the

training sessions? Is it CME? Because it's on a number of features. It's one on the low income subsidy, which really should be starting now. Nobody wants his patients who could be getting a drug benefit not to get it for lack of an application, especially because the low income subsidy benefit is complete benefit. No premiums, no deductible, no gap, minimal co-payments, and a full catastrophic benefit. The question of formulary changes: Of matching formularies to the patient's current drug lists. We would like input of the best way of interacting with the physician when it comes to that. And lastly, is just education about the insurance benefit of the Part D benefit in that this isn't only a matter of covering drugs that the patient is currently on. This is truly an insurance program, where it will cover drug needs as time progresses. I mean the statistic that is always thrown around is that for every decade after the age of 50, the average Medicare beneficiary has one chronic disease. At 3 chronic diseases, there is, statistically speaking, a very high chance of having very high drugs costs, at which point this benefit becomes more and more important. And since there's a penalty of 1% a month for not signing on from the date of eligibility, it's useful to remind people this is an insurance benefit, not an ongoing drug payment benefit. And it's useful to sign up early rather than late.

I think you've got the latest updates since the last time. Are there any questions?

Dr. Castellanos: Thank you, Dr. Kelman, are there any questions? Dr. Urata?

Dr. Urata: I had a couple come in stating that there was kind of a marriage penalty. The limits for a single person is $1200 a month income, and for a married couple it's something like $1800 a month. Is that true?

Dr. Kelman: Well, yes. These are following these complicated SSA rules. And technically speaking the theory is that it's cheaper for a couple, married couple to live together than two senior couples, so the drug cost needs have to be, that has to be factored in. But yes.

Dr. Urata: Yes. They're both sick though.

Dr. Kelman: I don't disagree.

Dr. Urata: They both have a bunch of medications they take. They share the rent, but not the pills. [laughter]

Dr. Kelman: Yes, and we don't want them to share the pills. [laughter]

Dr. Grimm: I guess the one question that I can see that will come up for our patients is the question of Do I qualify? Although it seems to be simple to us, is it clear on these—and I'll tell you most of these people who will apply for this will not be computer literate.

Dr. Kelman: No, it's a good question. And we had a pilot event in Oklahoma and people were given the applications. And it was sort of a progression. They were given the applications alone. They were given the applications with a volunteer, and then the last table with the Social Security Administration itself. Who had the computers. While it was not that simple, although a number were able to fill out the application appropriately by themselves. It took 10 minutes with a little bit of input, and then three minutes at Social Security. The advantage of the web tool is that it puts in the step edits if the wrong information is typed, it will correct it. And then it's a very quick turn around. I mean it's 6 to 8 weeks for the application but we expect 4 weeks for the online application. And so the application costs nothing to submit, and the answer will be relatively quick to come through.

Dr. Grimm: The cost will be borne by the physician, it sounds like to me.

Dr. Kelman: You mean to submit it?

Dr. Grimm: Yes. The time for my staff to sit them down, to walk them through it, because they're going to walk them through the computer thing, too. You're talking, this is going to be 10 minutes or longer for somebody to go through this with a patient.

Dr. Kelman: There's no question. We figure 10 to 15 minutes.

Dr. Grimm: So it is going to cost the physicians money to do this.

Dr. Kelman: Right. There will be time, certainly, time costs for whoever does it.

Dr. Azocar: I'm [off mike] region I am thinking about that population because particularly the minority population, elderly that may be difficult to reach because of their cultural or location characteristics, they sometimes are out of the main marketing ways, so you may require some [cough] to assure that as much as possible, that population can be reached and incorporated.

Dr. Kelman: No question.

Dr. Azocar: Just a comment.

Dr. Kelman: I agree. One of the things we're trying to do is to do events and outreach through adult daycare centers in various communities. Because they're sort of "of" the community as well. We

were out in LA, it was clear that there were Armenian adult daycare centers, there were Latino adult daycare centers, they were Pacific Rim adult daycare centers, and it was one way of getting into the community. But you're right. There are communities that are difficult to outreach in any standard.

Dr. Powers: I have a question and then recommendation. I haven't sat and looked through the toolkit well enough, but early on you mentioned that there would be a computer program where we could just type in the list of drugs, and it would tell us which plan covers those drugs. Is that in place now?

Dr. Kelman: This is a web tool—no, it doesn't exist now. That's being developed. That will have, it'll give a lot of ways of screening the plans; by premium costs, by formularies, by location, by pharmacy networks. In addition, this is the tool that will allow people to identify which plan they have been auto-enrolled into.

Dr. Powers: Because when a large number of my patients have no internet access. At that age group, and it's not just not having the access, but if you're not raised with computers, you're afraid of computers. And I'm, I've a computer in one of my exam rooms, and I'm happy to help them sometimes, but if it was easy enough. But how soon are we going to get that? Because they want to know now.

Dr. Kelman: Right. It'll be available certainly before enrollment is available. Hopefully at the time auto-enrollment becomes available. So it should be available in October.

Dr. Powers: And how will we find out that that's available.

Dr. Kelman: We can send it around to you.

Dr. Castellanos: Dr. Powers, you said you had one recommendation?

Dr. Powers: Yes. My recommendation and I will say that my patients know about this because they've heard about it at their senior centers, etc. So PPAC compliments efforts of CMS to disseminate information to the public about the Part D Benefit Program.

Dr. Castellanos: Are there any additional comments to that? I would like to also say that I think you've done a great job, both you and Dr. Bennett, of keeping us informed. And I think you really have done a good job on that. So is there a second to that motion?

[Seconds]

Dr. Castellanos: All in favor?

[Ayes]

Dr. Castellanos: Opposed? Dr. McAneny?

Dr. McAneny: I have some questions as well. One of the things that we currently see lately is that a lot of people who thought they had wonderful retirement benefits are discovering that their commercial programs are dropping benefits. And we expect, looking at the projections, to see this occur more in the future. So if a person has a current drug plan and it cancels, in particular, if it cancels after May of 06, that person would then have to pay the additional—

Dr. Kelman: No penalty at all. If they have creditable coverage, which the employers are required to notify their beneficiary of, then at any point in the future, that coverage is canceled, they join with no penalty, as if it had been day one.

Dr. McAneny: How did the subsidies for the employer plans work?

Dr. Kelman: In order to prevent, I mean it was a good question that came up when the Act was evolving—how do you prevent employers from just cutting out all their benefits? I mean dropping it. There's a 28% subsidy for employers that offer creditable coverage that they can get starting January 1 if they don't drop their coverage. And those for all drug costs between $250 and $5000. Now creditable has to be two prong; one, the coverage has to be as good or better than the Part D benefit, and secondly, the employer contribution has to be as good or better as the government's contribution. If they have that, then they can get a subsidy. And the subsidy looks like it's going to prevent, at least in the immediate future, many employers from dropping their benefit.

Dr. McAneny: Another question, as well as, there are a lot of rumors floating around about whether or not the Part B drugs, in particular the oral chemotherapies and other current things that are covered under the medical benefit as opposed to the pharmacy benefit, will those be moving over to Part D? Or will they be staying in Part B?

Dr. Kelman: Good question. At the moment, they're not moving anywhere. There is talk about it because, starting in January, there are going to be two drug benefits and there is a potential for confusion, particularly over the oral drugs, oral chemotherapy, oral anti-emetics and immunosuppressants for transplants, because all those drugs, in theory, could be B or D drugs. A oral immunosuppressant for transplant would be a B drug if the transplant was done on Medicare. It will be a D drug if the transplant

was done before the patient got on Medicare. At the moment, however, now that all the bidding has been in and submitted, based on the current system, and so, this is going to be looked at again on an active basis.

Dr. Castellanos: Are there any other comments?

Dr. McAneny: When they're looking at the TROOP, the true out-of-pocket expenses part, a lot of the time for folks who need assistance, we can get patient assistance for drugs, and it's really unclear at this point, whether or not patient assistance drug support will be considered part of their out-of-pocket expenses. And I as I talk to a lot of the pharmaceutical companies that help us out with our indigent patients, they say that the OIG still has not given final guidance to whether or not the manufacturers patient assistance programs will be part of this true out-of-pocket expense so that they can meet that deductible more quickly. Do you have any information on that?

Dr. Kelman: In terms of reaching "TROOP" and I think more guidance is being worked on. It's a complicated area, obviously, payments from a third party insurance company don't count towards TROOP. Government agencies policies don't count towards TROOP. On the other hand, qualified SPAPSs do count towards TROOP. And legitimate charitable contributions definitely count towards TROOP. So pharmacy assistance programs that are true charitable organizations would count towards TROOP. Fellowship funds would count towards TROOP. But there will need to be guidance as to what that means. And that isn't out yet.

Dr. Castellanos: Any other comments.

Dr. McAneny: I'd like to make a recommendation out of that last one. I'd like to recommend that CMS work with the OIG to give final direct guidance to allow the manufacturers' patient assistant programs to contribute to TROOP.

Dr. Castellanos: Dana, can you read that back please?

Ms. Trevas: The Panel recommends that CMS work with the Office of the Inspector General to give final direct guidance to allow manufacturer who offer patient assistance programs to allow the patient assistant program—

Dr. McAneny: Yes, that the money—that the patient assistant program is considered as part of TROOP.

Dr. Castellanos: Any further discussion? Call the question. All in favor?

[Ayes]

Dr. Castellanos: Opposed? I have two questions. One of the things we talked about last time was the 40 million Medicare plus recipients and the impact that's going to have on the physicians' offices. That's going to be a tremendous impact as you well know. I've been in contact with PhARMA and they say they're working very closely with CMS. I guess my question is what can and should we expect from the pharmaceutical industry for help?

Dr. Kelman: It's clearly to the advantage of everybody—PhARMA, the drug manufacturers, the PBNs, the plans, the insurance industry, physicians, advocates, to get as many people as possible signed up because it's a new way of paying for drugs that didn't exist before. The question is PhARMA has certainly been interested in becoming part of it, as have the individual manufacturers. I suspect that throughout their detail system, we'll be hearing much more of it at the level local physician's office. Beyond that, they haven't shared their plans with us. And I'm not sure they can.

Dr. Castellanos: And one further comment. You mentioned how you can reach the physician community. Dr. Mark McClellan came to our community several months ago and talked on two occasions. One, to a retirement community, and one to a nursing home. We found out about it the next day. It was not publicized in the medical community. The hospitals didn't know about it. The medical community didn't know about it. We found out about it the next day in the newspaper. And I think if he's going to be going to the communities, I think you need to let everybody know about it. If he's going to expend that much time and energy to do it, the public relations need to do a better job.

Dr. Kelman: I'll speak--

Dr. Castellanos: Dr. McAneny?

Dr. McAneny: I was curious as to how this would interact with hospice programs and with the IHS, which wasn't mentioned anywhere in the packet, the box that I received. And I always was confused in the folder number 5, where there didn't seem to be a line for any help from family members, and does that count against the patients, or can that be part of their true out-of-pocket expenses? How do those—

Dr. Kelman: Family contributions would count as TROOP. The hospice benefit—depends who's paying for the drugs now. Certain cases, hospice is a part A benefit. And in that case, it'll stay a Part A benefit.

Dr. Castellanos: Are there any other questions? Dr. Kelman, we really appreciate your comments. And please keep us informed and we'll look forward to hearing more about this program.

Dr. Kelman: Absolutely. Thank you.

Dr. Castellanos: We're right on schedule, so again, being a urologist, I think breaks are very important [laughter] so we're going to take a 15-minute break if that's OK.

Dr. Gustafson: We're glad you're not a psychiatrist. [laughter]

Dr. McAneny: We'll see how we really feel about it.

Break

Surgical Care Improvement Partnership Program

Dr. Castellanos: The Surgical Care Improvement Partnership Program is our next subject. As we continue on today's agenda, it's my privilege to introduce Dr. David Hunt. Dr. Hunt is a board certified surgeon and a medical officer in the Quality Improvement group at CMS. He is currently the government task leader for both the Medicare Patient Safety Monitoring System and the Surgical Care Improvement Partnership. Dr. Hunt has submitted three questions he'd like us to consider during his presentation. 1) How does SCIP align with the other QI initiatives, 2) Can or will SCIP move beyond the inpatient surgeries arena, and 3) Can SCIP data collection, again very resource intensive, and question is who's going to pay for that? Dr. Hunt.

Dr. Hunt: Dr. Castellanos, thank you very much. I'm really honored to have this opportunity to present to the Advisory Council. It's funny. Usually volume is never a problem, my kids tell me. It's the content that is always the issue [laughter]. I'm really happy to have the opportunity to present to the Advisory Council about the Surgical Care Improvement Partnership, or SCIP. As you've heard, my name is David Hunt and I'm a general surgeon and medical officer at the Centers for Medicare and Medicaid Services, and today I'd like to briefly make a credible case for our perspective at CMS on the measurement of surgical quality and its implications for the practicing surgeon. Five years ago, a representative from CMS would have very little to offer in this regard. Three years ago, we could highlight our embryonic work in surgical infection prevention, but today I can really stand before you and present a bold plan to work with a number of stakeholders on improving the safety of services to our surgical patients. Now it may seemed as though I just changed the focus of my discussion from quality measurement to patient safety, but

that's one of the first and foremost points I'd like to make regarding our perspective on quality, namely that we subscribe to the principle explicitly stated in the 2003 IOM Report on patient safety data standards. In that report, Paul Tang and Molly Cole and the group brought home forcefully the message that many of us in the quality groups have quietly preached for some time, namely the patient safety is indistinguishable from the delivery of quality healthcare. I'll say a little more on that in just a few minutes, but I think it's important to acknowledge a few realities. The first is that patient safety isn't a new topic for surgeons. I'll discuss a little more on our history of that in a moment. But suffice it to say that safety and quality have received a new sense of urgency. This urgency is in part due to the confluence of market forces to demonstrate value in a system increasing in technologic sophistication, yet lacking the commensurate capacity to measure and in turn improve the rate of fundamental defects as measured by patient harm.

Before I go on, let me step back and outline my take home messages. My 17-year-old daughter once gave me some advice on public speaking. She said, Dad don't take this personally, but you have to bottom line any audience very early on. When you speak for more than 5 or 10 minutes, you become boring and tedious. [laughter] So take Dana's advice and bottom line you. The first is that surgical quality measurement and improvement must be led by surgeons. The second is that surgery is a team sport, and surgical quality improvement is no different. Any progress we have lives or dies solely on the strength of our team. And third, I won't say that all I can offer you is blood, sweat, toil, and tears, but the path forward requires a system, tremendous resources and courage. Now we'll need whopping doses of that last because our major goal is to reduce preventable surgical morbidity and mortality 25% by 2010. To do this, we're guided by some fundamental principles of quality and safety. In SCIP, we subscribe to the cornerstone of surgery, first stated by Hippocrates in Epidemics I, where he wrote: As to diseases, make a habit of two things; to help or at least to do no harm. The beauty of this statement is that it firmly establishes an upper and lower bounds; to help at the high end and to do no harm at the lower. And when Hippocrates says "Make a habit," today, we would say, "make a system." And wonderfully this rule provides an answer to a question we hear a lot at CMS. What is the relationship between patient safety and quality? Well, this is how we see it. In this model, all elements of safety are within the domain of quality, but there are aspects of quality outside of the domain of safety. Now, CMS has not always had a coherent concept of quality or safety. So the history of the evolution of the CMS quality improvement program is somewhat irregular. But

I believe we found our voice in a very simple vision. This is our vision: To assure the right care for every person, every time. Now the first question everyone asks is, "What do you mean by right?" And I think the IOM answered that question pretty well in their 6 aims for improvement. Right means safe, effective, timely, patient-centered, equitable, and efficient care. In SCIP, we've modified that a little bit by pairing those IOM aims as is true in all of surgery, we feel comfortable doing that because, well, surgery's special. [laughter] You see, in the world of the operating room, I can tell you that you should be no more efficient than you can be safe. In the world of surgically correctable disease, effective treatment is almost always synonymous with timely treatment. And in the world I live in, and as the *New England Journal of Medicine* clearly reiterated last week, you can't be patient centered without being equitable. So, we've collapsed six degrees of freedom into three. And having said that, what is our strategy? In the quality improvement group, we've identified four key strategies to make this vision a reality. They're performance measurement and reporting, systems adoption and use, process redesign, and organizational culture change. I'll speak in depth about these in a moment, but earlier I mentioned that surgery is a team sport so these strategies are of no use without a strong tactical team.

This is our team. And this team is the real value proposition of SCIP, because we have the active engagement of everyone on this slide. The stars truly lined up when we set about this journey, because when we asked the American College of Surgeons about working with us, Scott Jones, the Director of Quality and Research at the College told us that they were well into a project working jointly with ARC and the VA to test taking the VA's national surgical quality improvement project or NSQIP, the NSQIP program to the private sector. The College recognized that in surgical quality improvement, an effective proof of concept was alive and working everyday in the Veterans Administration. The VA has actually led the most comprehensive, innovative nationwide surgical quality improvement effort in the last 50 years. Through NSQIP, they were able to demonstrate a 47% improvement in morbidity, and a 27% improvement in overall mortality. So with this team in mind, let's talk about our strategy, and I'll begin with measurement and reporting.

Now many of you know that the modern era of quality measurement and reporting as a formal discipline has its origins in the work of Walter Shewhart, William Demming, and Joseph Duran. These men are brilliant and I never want to ever make my comments suggest anything but the utmost respect for their

work. But I do take exception with the current trend to frame all health care quality improvement in the context of the industrial experience, notwithstanding the work of Avedis Donabidian, it's important to emphasize that industrial strength quality improvement techniques lose something in the translation to health care. For all of its merits, industry based measurement and quality improvement can only apply the concern of an actuarial ledger. When interventions and improvements are discussed, they're done with the dispassionate cost benefit analysis of industries comfortable with bending sheet metal. In short, it's been my experience that typical industry quality improvement can become obscene when applied to the individual patient. So surgeons have to lead surgical quality improvement. And while we lead, we know we can do so comfortably knowing that before Demming, before Shoehart, before Duran, surgeons were leading quality improvement on the exact same scale as our needs today. The names of Bill Roth, or Lister, or Halstead aren't revered just because they knew how to tie silk. They're legends because they met the challenges of quality in their day. Now I don't know if anyone can say that today we have the equivalent of Lister or Halstead, but on our team, we've been working closely with the leaders in American surgery. Now having said that, I don't want to give the impression that it's nothing but peace and harmony in SCIP land. The only universal truth in SCIP is that it takes everyone out of their comfort zone. At the SCIP steering committee, we've had an animated discussion on every aspect of the project. Case in point: At the heart of any effort to change must be a system to measure progress. The approach to this subject really represented a defining point for the SCIP partnership. You see, CMS in the QIO program traditionally worked with process measures; the percentage of patients receiving antibiotics on time, or the percentage of women having mammograms who were eligible. Yet, the backbone of measurement for many of our partners is outcomes based. As surgeons, we know all too well that outcome is a derivative of process. But we also know that none of our patients consent to surgery just to have a good process. Clearly the special nature of surgery warranted a measurement system that included outcomes. In the end, we concluded that a balanced surgical quality improvement program must contain measures of process and outcomes.

Now within that balanced approach, what areas of post-operative complications would we first address? In SCIP, we looked again at the work of the VA and have chosen to stand on four broad clinical areas. Here is a slide of data from the VA's NSQIP program that basically gives the relative rates of isolated complications in surgery. We selected surgical site infection, perioperative myocardial infarction,

post-operative venous thromboembolic disease, and post-operative respiratory complication. This was the clinical nucleus of the three-state SCIP pilot that we began in 2003 and will be the focus of CMS's surgical quality improvement in the eight scope of work, which runs from August 2005 through July, 2008. A fifth domain, ESRD vascular access was co-opted from a parallel project at CMS. This project, known as Fistula First, has the goal of increasing the use of primary AV fistulas for our ESRD population to 66%. Time precludes providing much detail except to highlight one point about the Fistula First component. In this area, the United States provides the worst quality in the industrialized world. So within these clinical domains, what are some general rules for refining our measures? The first rule is that each measure rests on guidelines with a solid level one evidence base. Our representatives from anesthesia have been very good at holding our feet to the fire with regard to this standard. But to some extent, we're taking everyone out of their comfort zone, so we agreed that beyond the solid evidence, there should be general acceptance or face validity for each measure. That's not to say that we expect everyone to agree. We just wanted to have a generally consensus view for the start of this very ambitious project. And third, to as great an extent as possible we try to quell the cacophony of competing national quality improvement programs. Time and time again we hear from physicians and hospitals that they can't keep up with the flavor of the month barrage of programs, be it from CMS, the Joint Commission, IHI, or the CDC. In SCIP, we've brought all the major national surgical quality improvements under one roof. We have gone to an extraordinary effort to assure measure singularity with the joint commission, IHI, CDC, and both the ACS and VA versions of NSQIP. This means that we've received commitments where our measures are common they will be identical. In practical terms, this means that the ACS NSQIP program has adopted in total all of the SCIP process measures, and our outcome measures are directly derived from NSQIP. For example, the SSI measures of the IHI 100,000 lives campaign are the SCIP infection measures. And the Joint Commission is committed to aligning their measures with ours. Operationally to work in concert, these commitments represent a tremendous overhead cost for each of our organizations, but the health care community really expects nothing less. I can't provide detailed discussion on all of our measures, but let me summarize the main modules as succinctly as possible.

In surgical site infection, we're looking at timely antibiotics, the correct antibiotics, prompt discontinuance of antibiotics, proper hair removal, normal glycemia in cardiac surgery, normal thermia in colon surgery, and our outcome measure, the number of surgical site infections.

In venous thromboembolic events, we're looking at the number of pulmonary emboli and DVTs. In addition, we have two very simplistic sounding process measures, based primarily on the surgical procedure they are, was the recommended VTE prophylaxis ordered? And Was it given? The devil is in the details was never more true than in our VTE work. We know that there are considerations other than the surgical procedure when choosing VTE prophylaxis. But our three state pilot clearly demonstrated that the burden of collecting that information is close to prohibitive for hospitals. The result is that absent exigent clinical circumstance, our measures provide a minimum level of safety in select surgical procedures. Does that mean that can additional co-morbid conditions warrant prophylaxes for additional procedures? Well absolutely. But given the information set available in SCIP, our VTE measures comport with the best evidence-based guidelines.

In perioperative MI, we're looking at the number of perioperative MIs for outcomes. And under process, these measures are simply the continuation of beta blockers for those currently on these drugs, and the institution of beta blockade for those at greatest risk for perioperative MI.

When we started SCIP, we all hoped that we could develop measures that address the very broad and significant complication of post-operative pneumonia. In working with our technical expert panels, we quickly realized that we could not readily come to agreement on the generalizable case of post-op pneumonia. So we narrowed the category to ventilator associated pneumonia, which has a number of well-documented randomized control trials demonstrating effective interventions. This is just one instance of many where our best intentions were narrowed by a limited evidence base. It's effectively and inescapable truth that our policies of improved national health care quality require the broader adoption of information technology. Our three state SCIP pilot just confirmed what we all knew. For SCIP, data collection burden was significantly reduced by information technology. The average abstraction time for a paper chart was 40 minutes. One hospital that integrated our data collection specs into their electronic health record had an average abstraction time of 10 minutes.

Now to process redesign. In his most famous work delivered to the graduating class of the Yale Medical School in 1904, William Stewart Halstead asked, “How can American surgeons achieve the quality seen in the clinics in Germany and Vienna?” He asked, “Why did Germany embrace the concepts of Lister and aseptic technique, while Lister himself struggled to promote his own standard in the United Kingdom?” Halstead concluded that the ideology of the poor outcomes seen in the surgical wards of the United States was fundamental to the systems of health care delivery. Halstead went on to revolutionize surgical training in the United States and the Halstead system is largely credited with moving the epicenter of surgery from Europe to the US. In 1904 of vacuum in the quality of care in our surgical wards call for a solution by surgeons, and in 2005, an identical call to meet a remarkably similar need is being made. Only this time, the pressures are external. Consumers, purchasers, insurance plans, public and private are demanding measurement, reporting, and improvement throughout health care. These demands actually distill down to one common theme; Halstead’s them in 1904. We need a system. Well we’ve continued this theme in our SCIP measures. As a general rule, SCIP advances systems measures, measures that require engagement of more than one component of the surgical services for reliable execution. The delivery of antibiotics of within one hour before incision is a great example of a systems measure. To be reliably successful requires a complex choreography between pharmacy, pre-op, holding, anesthesia, the circulating nurse, and the surgeon. For hospitals with any surgical volume, this is the prescription for process improvement on the system.

From physics we know that an ordered state of systems has a much higher overhead. A higher regular operating cost. So what’s the opportunity for return of investment of increased overhead. This slide shows our current compliance with guidelines and the SCIP modules of infection, MI, VTE, and ESRD vascular access. We don’t have good numbers regarding the question of ventilator associated pneumonia. From this slide, you can see that we have a significant opportunity to improve the care of our surgical patients. But many respects, I know that I’m preaching to the choir. And to achieve our goal, we must persuade the congregation. We must be willing to support a change in the culture of American healthcare. We must convince components that they must act in concert. Medicine is too complex to do otherwise.

Now many times I hear the complaint that by defining process measures, by insisting for working in concert, using evidence-based guidelines that we’re purporting or promoting “cookbook medicine.”

Cookbook medicine. I take particular exception to that argument. Why? Because no one argues about cookbook medicine when we teach ATLS or ACLS. No one rails about cookbook medicine at the American Board of Surgery Certifying exam. Now, I understand that many will defend the absolute autonomy of the physician to practice in any manner they see fit. So let me be the first to say that right now, I am a practitioner of cookbook medicine. In fact, let me show you some of my culinary library. These are my cookbooks and nothing we measure in SCIP is inconsistent with either the spirit or the letter of these culinary texts. The training to become board certified requires an indoctrination in a solid evidence base, with core requirements, well-defined expectations of performance and conduct. This training was neither freeform, coincidental, nor dictated by anecdote. Why should the rest of our careers be any different? To the detriment of our patients' health, the most common explanation I can find is humorous. While the creation of a reliable fault-tolerance system is not the sole responsibility of the physician, it is the responsibility of the attending physician to accept the support of the systems that SCIP will insist that hospitals develop. Now the nature of that insistence is changing and has taken center stage in American health care. We've gone beyond questions of just quality improvement and moved into public reporting, and that brave new world of pay for performance. Many have asked if pay for performance has a proper place in this discussion. And some ask if this entire discussion is premature. But Dr. McClellan has instructed us that open and frank discourse with stakeholders must guide any pay for performance model. So in that vein, the question of prematurity must be asked and answered. Well, let me start off by saying that my formal economic training occurred when I was 7 years old. My mom taught me how to count my change after I bought ice cream. So obviously in this company, I'm a rank amateur. But I have read a little history and I know that surgical pay for performance was explicitly described 3600 years ago in the Code of Hammurabi. I know that the Scottish economist, Adam Smith, makes a strong case for a differential market value to ostensibly the same service, based on the perceptions of the customer. And he states this while acknowledging that quality measurement will always be a point of dispute. I offer these historical facts to suggest that while we devote 15% of our gross domestic product to health care, our current payment policy is actually an anachronism of unprecedented magnitude. And I'm not alone. At our last Clinical Congress of the American College of Surgeons, I shared the stage with Charles Mabry, Shukri Khuri and Reed Tuckson, the Medical Director of United Health Care. At that panel, we presented SCIP as

the future of surgical quality improvement. Well, Reed thought as a starting point SCIP seemed to be as good as any and better than most. But he wasn't singularly impressed because he'd heard this song and dance before. He let us know that from United's perspective, it's not about plans, it's about execution. He was very pointed and clearly told us that the surgical community does not have the luxury of time. That United, like many other companies is willing to work with clinicians as they develop pay for performance policy. But he also warned if we as surgeons can't get our acts together and present a coherent generally accepted, clinically based measurement plan, the folks in accounting have a solution. He couldn't be more clear. Time creating the perfect solution will be a waste.

Now I've tried to formulate some questions that may be useful. I've briefly covered the first. How does SCIP align with other major surgical quality improvement initiatives? The brief answer is that from the IHI hundred thousand lives campaign to the ASC NSQIP program, they fall under the broader umbrella of SCIP. Second, almost half of surgery is done in the outpatient setting. How does SCIP address this? Well, our first priority was establishing a program in the inpatient domain. That's what's being launched this month, actually. As we move on that front, the SCIP steering committee has recommended that we explore outpatient quality improvement, an exploration that must include robust data channels to the surgical office. And last, a question that I frequently get from hospital staff and administrators: Who's going to pay for all of this? As you can see, many of the costs associated with SCIP are borne by the steering committee. But in today's world of tight margins and limited resources, there is still concern about providers subsidizing data collection and process improvement aspects of SCIP. The last 2 bullet points. So for hospitals, the question of who pays is still an important one. But a complete analysis of that question can't just look at a future system. The ledger has to include current expenses. Now this data comes from work in Michigan, where using the NSQIP data base, and the hospital's internal cost accounting system, they were able to identify the cost to the hospital per case, for each of these major groups of complications. Please note that these are actual costs, dollars the hospital spent, not charges. We're talking about $8200 for a surgical site infection, cardiovascular complications range about $13,000. Respiratory complications are $54,000 and above, and thromboembolic complications per case here, about $28,000. Looking at these numbers, any hospital CFO worth their salt can tell you that for Medicare patients, under PPS, they are

paying dearly in real dollars for complications. So in first analysis, we can say that hospitals are really paying for the current system and in SCIP, we're recommending in an improved bottom line.

But that's not half the story. The first time this question was asked to me was from a general surgeon from Robert Wood Johnson Hospital up in New Jersey. And I didn't tell him these numbers. These are numbers for CEOs and CFOs. I'm a surgeon. So let's go over the balance sheet that really matters. Last year, 56,233 Medicare patients paid the bill with an infection. Over 17,000 beneficiaries paid with perioperative MI. And close to 14,000 tendered a VTE to cover the costs of our current system. And make no mistake, these are true costs. But there's one more number to remember. In the Medicare system alone, it seems as though 13,000 families needlessly lost a loved one, and paid the real cost of our current system. It's antithetical to our profession that we consider the value of pain and suffering or put the price on a life, no offense, but that's a lawyer's job. So when I get a question from a hospital administrator or a doctor about who will pay the bill for this system, who will pay for SCIP? I always refer them to the statements of those paying the real bills for the current system. Their response is unambiguous. Our patients are very, very clear. They say, and I quote, "enough." So with that, I'll stop my presentation and thank you very much to the opportunity to present. And if we have any time, I'll be more than happy to answer questions.

Dr. Castellanos: Thank you, Dr. Hunt. I like your comment about surgery's special. I think you might have some other people in the room that will question that. [laughter] But I also agree the devil is in the details. Are there any questions the Council has?

Dr. Przyblski: Unfortunately, I have a long series of questions.

Dr. Hunt: Not unfortunately.

Dr. Przyblski: I'll keep them brief and to the point. One is are these measures going to be applied to all different types of surgery, or have you selected specific subsets of surgery? I'm a practicing neurosurgeon so that's—

Dr. Hunt: OK, we had selected specific subsets of surgery. In our surgical infection prevention project, was really run through the seven scope of work, we looked at five major broad categories of surgery, colons, hysterectomies, vascular procedures, cardiac procedures, hip and knee. So for in SCIP we realized that that was a very narrow subset and we've tried to apply these measures where appropriate to the broader range of surgical procedures. Now, for example, pre-operative hair removal in neurosurgery.

That's not necessarily a measure that you would necessarily want to be held to a standard to because of the special circumstances of your operative field, but for colon surgery, for groin surgery, obviously applied. The same is true for other applications of VTE prophylaxes, beta blockage for perioperative MI and post-operative ventilator associated pneumonia. So each of the measures that we have actually have a specific subset of surgical procedures that we're looking at. Now we have significantly broadened that number of surgical procedures beyond the five that we're looking at for surgical site infection because we really were able to come to a pretty good consensus from the guidelines writers on what they can be applied to.

Dr. Przyblski: With respect to infection, are you also looking at re-dosing of antibiotics for longer procedures, so in neurosurgery, for example, where you may have 8-, 10-hour procedures, yes you may have given it at the right time, but if you haven't re-dosed it during the case, what you're going to measure in the outcome, i.e., surgical site infection, may not be reflecting re-dosing.

Dr. Hunt: Absolutely. And this is a great example of where the detail of the collecting burden really reached too high a point, and unfortunately we had to make some compromises. The issue of re-dosing antibiotics was one that came up pointedly. The question is how do we actually make a streamlined approach to have the hospital and the hospitals are collecting this information, be able to enter in information of the re-dosing of the antibiotic. To be honest, that had to go by the wayside, just because it didn't meet our threshold in terms of our burden for the hospital. But we definitely support this, and all of our literature, and all of our information and our tools, speak to these issue of re-dosing.

Dr. Przyblski: On the VTE side, I don't know if any of that is applying to neurosurgery or not, but certainly a lot of the things that we do, small amounts of post-operative hemorrhage that can be related to prophylaxes with anti-coagulants can be substantial burdens in causing re-operations. Is that being considered in neurosurgery or other areas?

Dr. Hunt: Absolutely. And we have, beyond our steering committee, we have a very, very broad technical expert panel that has representatives from neurosurgery, orthopedics, a number of different specialties and that was one of the issues that came up. In our guidelines for VTE, we actually referred to the ACCP guidelines that were recently updated, chess, we actually had the benefit of Bill Gurtz, the editor for that lead article on the panel. And basically what we've done is we've applied a calculus where the appropriate VTE prophylaxes meets that measure, or meets that surgical procedure. So in the cases of

neurosurgical procedures where you have that closed space spinal operations, cranial operations, at least the bare minimum is considered something like sequential compression devices, not all VTE prophylaxes isn't pharmacologic. We really do, in a lot of the cases, actually speak to the non-pharmacologic measures with that in mind.

Dr. Przyblski: OK. And then finally, although I would commend you on wanting to base things on class 1 evidence, I hope that there's a realization that a lot of things in surgery really don't have class 1 evidence to go on and that you may have to accept class 2 evidence or as you set the consensus and face value in making recommendations.

Dr. Hunt: I can't tell you how often, when we started this process, back in 2003, we had really, really broad ambitions. And so many times, when you and I hold as absolute truth, we found that there's no randomized control trial to approve it. Now everyone knows there's no randomized control trial that will show that aspirin cures a headache, so there has to be some balance of what you decide to do. So we haven't relaxed the standards, but we do take that into account. Things that really don't comport themselves well with randomized control trials, or are so well established within the doctrine of the surgery, we hold as truths. But on the other hand, it was very, very difficult. And one great example will be the use of normal glycemia in cardiac surgery. Our standard is a glucose level in post-operative day 1 and post-operative day 2 of 200 or below. Now if you speak to any practicing endocrinologist, or cardiac surgeon, they'll be able to tell you, that's very high. Actually a lot of groups are aiming for 170 and 140 actually, is more appropriate. But having to go in front of large groups of physicians and to be able to say we know that this is absolutely true because we can prove to you that we can show improvement in the rates, we had to make some compromises. So we're trying to have a balancing act with that, and I hope that we make sense as we move forward. But one of the reasons for coming in front of a group such as this is sort of as a gut check, a validity check, does this make sense? And if it doesn't, you got to let us know.

Dr. Przyblski: Thanks very much for time.

Dr. Hunt: Sure.

Dr. Castellanos: Are there any other questions? Dr. McAneny?

Dr. McAneny: I think, first of all I'm glad to see you still have both your hands, [laughter] and I think that the point is well taken that only surgeons are going to be able to come up with a performance

measures that are appropriate for surgeons, and I think that's true, but it breaks down to each of the different subspecialties. There's no way that I could write the performance measures for a neurosurgeon, etc. And I think that's very valid. And I think also that as you look at these measures, the value of them will be within a given system, whether that system is a physician practicing independently, or a physician practicing in a system to improve what he or she does. However, there's always this tendency to want to publish ratings of people and when you start publishing ratings and comparing one group of patients in one system with a group of patients in the others, then you run the risk of saying the patients who happen to be living in Marin County, where I understand everyone is wealthy and well-fed and has no underlying alcoholism or other problems, and therefore they do very well, is going to look very different from someone who is their surgical population are people with significant co-morbidities. If you're looking at infection rates and somebody comes in with a ruptured gall bladder and they also have an infected leg already and they have other things going on, or they've been having unstable angina, your rates could look really bad. And I could see people saying let's see if we can send those patients over there. So I'm very concerned about how you will deal—the question is how do you plan to deal with the urge to start publishing data and letting systems or companies or insurance plans start using this data to try to compare your apples with my oranges?

Dr. Hunt: That's an excellent question. And actually, we took our lead from the work in the VA system. The VA Program is actually almost exclusively an outcomes based program, and over the course of the last 15 years, they probably have developed the best risk adjustment model that the surgical community has. So we, our risk adjustment model really falls back on that of the VA's program, which has a pretty solid track record in the surgical community. But beyond that, and one thing that's most important, the question of process versus outcomes measures came up and that really feeds to the answer in this response. That is to say that for in many situations, the co-morbid conditions actually is tough to figure out and we'll rely on the risk adjustment strategy. But in so many instances, the process of actually delivering care should be relatively uniform, regardless of any additional co-morbid procedures. Did the patient get the antibiotics on time? That's really one of the beauties of process measures. They require no risk adjustment. They require no caveats with regard to who the patient is when they came in. Everyone that has undergone a cholecystectomy really needs antibiotic before hand, and they should be delivered one hour beforehand. So

hopefully, we've been able to balance that question. The answer is that we balance that question with one, a solid risk adjustment strategy with regard to the measures of outcome, and two, really relying a lot on process measures. But beyond that, at CMS we really have recognized that there are three tiers of measurement strategy. The lowest level is for quality improvement. We have a very, very broad set of measures that are useful for quality improvement. A higher standard are those that we use for public reporting, that is to say information that will go out to the public. And still the highest standard yet would have to be those that we ever decide, if we ever decide, to link into Pay for Performance. I don't want to even begin to suggest that all of the measures in SCIP are suitable for all three tiers. In fact, when we originally designed SCIP, the whole thought was really just at the hospital level, quality improvement point. But we have recognized that there are measures that are very, very applicable, or suitable for public reporting. The antibiotic measures, actually, are a good example of that. And we do believe that moving forward some of the subset of measures in SCIP would be suitable for Pay for Performance.

Dr. Castellanos: Are there any other comments? Dr. Azocar?

Dr. Azocar: I was going to comment in the same line that Dr. McAneny expressed to elegantly, that when looking at outcomes, and like you say also, it's very difficult to compare populations where there are differences in co-morbid and compliance. Basically, even pre-op and post-op, and that may affect, or then, you may having the same team, the same effort, the same investment, you may get significant differences in outcomes between two populations with different characteristics. Mainly, inner city populations, for example, are compared, so that may be a factor consider when, especially when that's related to Pay for Performance.

Dr. Hunt: And that's one reason that the work that the VA has done is such a wonderful resource. Twenty years ago, no one would ever suggest that the VA had a pristine population of patients that were all the best candidates for surgical procedures, and they were able through the course of their work in NSQIP to develop a risk adjustment model. And their risk adjustment model, I should have brought the slide, actually is very effective and has been peer reviewed and tested for at least 15 years in the surgical community that shows that 1) volume alone isn't the criteria by which you can measure quality, and that the bottom line outcome definitely isn't the final measure on how you measure quality. That there has to be some risk adjustment, that there has to be some consideration of the co-morbid conditions of the patient.

And I really can say that we've relied very heavily on the team of Bill Henderson, Shukri Khuri, Jennifer Dailey in their initial development of the NSQIP risk adjustment model that is it very solid. But again, measures, this discussion as far as what are appropriate measures and how do we actually compare two different hospital systems came up time and time again and while the college of surgeons looks very favorable on just outcomes, we really have to say that there has to be some other measures in there and so we came to that balance of process and outcomes. And regardless of the population that comes into surgery, the process of health care really should be relatively uniform. So hopefully, we can give a fair and equitable balance when looking at different hospital systems. We know that your surgical infection rate may be a little bit different between hospital A and hospital B, but with regard to the things that we know prevent surgical site infection, everyone has an equal opportunity of achieving those goals. Did you give the antibiotics on time? Was there normal thermia in situations of colon surgery? Did you maintain the glucose level at proper rates? Regardless of what the outcomes were, the processes of care really have to be in place. And that's why we really were trying to develop each of our measures, and I hope that we've been able to hit the mark. Each of our measures have tried to be systems measures. That is to say no one component in a hospital can really make these measures reliably happen. It really has to be a situation where the hospital, and we're encouraging the CFO and the CEO to roll up their sleeves and get down with the operating teams and come down and give the resources to allow these measures to reliably be met. That is to say, you can't expect that we'll be able to get antibiotics within one hour of surgery if you put restrictions on how pharmacy delivers things on time. The CFO and the CEO, they're the ones that can smooth out those barriers. And so we've been able to say that to a wholesome discipline, within SCIP, the measures that we have will really require, in a way we often refer to it is tough love, will require more than just the OR team, more than just the circulating nurse to roll up their sleeves and get involved. It really will be a broad category of services across the hospital that will be required to actually meet these measures.

Dr. Castellanos: Are there any other questions?

Dr. McAneny: A lot of what you're talking about and your third question there, data collection, is very resource intensive. And it's not just SCIP, I think this applies to everything. It applies to the coverage with evidence development, it applies to clinical trials, it applies to everything. Data collection either requires expensive systems, which generally are purchased by a physician in their office and the benefit

goes to the United Health Plan or someone else, or they're purchased by a hospital, they're still expensive. Or it's the time consuming cost of paying a person to sit down and abstract a chart. If you get inaccurate data, that's probably more expensive. So I think that if data collection is going to become part of the cost of doing business under a new system, that I think it is necessary for CMS to lead the way to say this is one of the practice expenses that you incur if you wish to practice surgery, oncology, neurosurgery, urology, anything else. And a system needs to be figured out to accurately assess that practice expense and build that into the compensation system, because otherwise it becomes an unfunded mandate that we simply will not be able to afford.

Dr. Hunt: Which is another reason that we initially went through the SCIP process in a phased way. That is to say, right now the burden of data collection for SCIP is on the hospital itself. And CMS isn't just saying, it's on the hospital, you have to figure it out. We have provided a number of tools, a number of methods to help and assist the hospitals in actually acquiring the skills and the resources in terms of collecting that data. The issue of going to the individual physician's office is an important one and actually in the three-state pilot that we had, one state, Kentucky, actually had a group of surgeons that already had a robust infrastructure for collecting surgical office data in place, and I can say for sure that that group was read by Hiram Pope and Quality Surgical Solution. They were actually, the data from them was very, very robust and was absolutely wonderful. So as we move forward, and one of our plans in terms of special studies and looking forward in SCIP and moving to the outpatient sector is trying to figure out what is the best way of being able to open up data channels from the surgical office, because we know a lot of infections, that's where you're going to find them out. We're blind to much of the surgical site infections if we just look at inpatient, and so we are going to explore that specifically.

Dr. Castellanos: Barbara, you said you had a recommendation?

Dr. McAneny: Yes. I'd like to say PPAC recommends that CMS recognize that data collection is expensive and that if it becomes part of the cost of doing business, then it must be accurately compensated by CMS and other carriers.

Dr. Castellanos: Are there any comments to that recommendation? Seeing none, let me call question. All in favor?

[Ayes]

Dr. Castellanos: Opposed? Again, my only comment is what Barbara has. In my specialty, urology, 85% of our surgery is done in the outpatient arena. And that needs to be captured. And we've talked about infections and we've had a difficult time in our community collecting that data. But perhaps IT is going to be important to get this resource. Dr. Hunt, we thank you. Very much.

Competitive Acquisition Program

Dr. Castellanos: The next program is Competitive Acquisition Program. We now continue our presentation with the most up-to-date information regarding the Competitive Acquisition for Drug Final Rule. May I introduce Amy Bassano, recently appointed Director, Division of Ambulatory Services, Centers for Medicare and Medicaid Services. Prior to joining CMS Amy worked for 4 and a half years in the Office of Management and Budget, as the lead analyst for Medicare Part B and D, and prior to 2000, she was a Part B issue analyst in CMS Office of Legislation. Please note that in addition to the PowerPoint presentation, a copy of the CAP Physician Election Agreement is included in your briefing book under Tab G. Amy?

Ms. Bassano: Thank you. Well we've had a lot of activity in the CAP world since we last met and spoke, and I'll try and give you a brief overview of the events that have occurred and then I'll be happy to take any questions you may have. We published an Interim Final Rule to the CAP Program on July 5th that has a 60-day comment period. We received a lot of comments requesting doing this as an interim final rule, since there are many open issues and this is a new program and that's proven to be a good decision, because as we have gone forward, we've recognized that we've gotten lots of comments on lots of issues that we hadn't anticipated, and really had to operationalize this program. So we are collecting comments, or accepting comments until September 6th, so a couple more weeks. A couple of the big decisions or big policies outlined in the Interim Final Rule is that there will be one national acquisition area. The law allows us to have multiple areas throughout the country, but we decided to use one area so the vendors would have to provide services throughout the entire country and the territories. We received numerous comments on this, and generally in support of going from one acquisition area. The vendors who could meet the quality financial standards that are outlined in law, all are nationwide providers, and that they would not have, there would not be much of an issue for them to provide for all 50 states. So we went with the national acquisition area. We also went with one category of drugs. Again, the law allowed us to have multiple

categories, but we decided to, at the beginning of this program, to have one category and those would be all, we tried to be as comprehensive as possible and have as many drugs in there across all specialties. The number here says 181 drugs, although that is being corrected. It's really only 180 drugs. One drug we realized was on, the new drug list, and shouldn't have been because it was not a physician-administered drug, but there's 169 drugs in the mean category, and there's 11 new drugs that we wanted to include. We thought they were important to include, but we separated them out. The vendors will be required to bid on them, but because we didn't have weights for them in order to bid, we kept them separate, and those bids will be accepted as individual bids of no more than 106% ASP. There are some other processes we finalized in the rule. As I just mentioned, the composite bid, the average of all the bids of the drugs cannot exceed 106% of ASP. We had proposed that in the proposed rule, and kept it in the Final Rule since the, to be equivalent with the ASP side of the drugs. We also outlined the vendor bidding process, formalized the process for that and vendors are required to have 3 years experience, and meet certain financial and quality standards in addition to having their bids not to exceed 106% of ASP. By law, we're required to choose at least 2 vendors, and we propose to take no more than 5. So when we select vendors, we'll be selecting between 2 and 5 vendors for the one national acquisition area. The physician election process is generally, and I'll get more about this in a moment, to occur in coordination with the PARDOC process in the fall. Physicians would have an opportunity to select between the vendors we've selected to participate in CAP and they would select one vendor and we'd be contracted and committed to that vendor for that particular year. Every year, they could choose a new vendor, but the vendor would be for that one particular year. Dr. Castellanos has mentioned the physician election form. We did provide that to you. It has gone through the paperwork process and was published in the *Federal Register* and was soliciting comments on that. Although since we will be delaying getting a little bit ahead, but we would be going through that process again when we actually do conduct the election process. So we would be interested in hearing any of your comments on the particular form. We tried to make it as simple and straight forward as possible. Beneficiary co-insurance, the vendor is required to collect this. We received lots of comments on how the vendor could go about collecting the co-insurance and if they can waive it. And we tried to make clear in the rule that they can. Vendor's required to collect the co-insurance but they can waive the co-insurance if they meet the Inspector General's requirements for being able to waive it, but they made an attempt to

collect it, there's financial hardship, it's not done on a routine basis. We also are encouraging vendors to set up programs to help beneficiaries with their co-insurance if they cannot collect it and to help them do that and to direct them to physician assistance programs. We received numerous comments about how the CAP vendor should be licensed and what their requirements are to be. We clarified or outlined in the Final Rule that it would be up to state law in terms of licensing. We did not intend to preempt any state law. So if a state law requires a vendor to meet these requirements, it would be a pharmacy or a wholesaler, they would be required to be licensed appropriately in those states. And that would be something that they would be telling us in their application, the licenses required in their particular states. Another issue is the definition of an emergency. There are certain statutory requirements of in order to provide drugs in an emergency situation, including that the physician could not have anticipated the need to provide the drug on that particular day. And then this situation, the physician is allowed to take drugs from their existing stock, provide it to the beneficiary, and then get it replaced by the vendor. But one of the other requirements is how to determine what the emergency is. And we left that as broad as possible and left it up to the physician's clinical judgment if they determined if it was an emergency situation or not. There are numerous other issues in the rule, including claims processing. We are going to be using a designated carrier to process the claims for the CAP vendor, but physicians will be submitting their drug administration claims as normal to their local carrier. There's also a dispute resolution process to help vendors and physicians resolve any issues that may come up in the billing process or in the ordering drugs. And those are generally the major issues. Like I said, we published that on July 5 in the *Federal Register* and began the bidding process immediately upon publication of the Final Rule. It was to be a 30-day bidding process. And bids were due August 5th in order to discuss the issues and the process with the vendors, we held a conference call for potential vendors on July 8th. We had a great participation and lively discussion of the different issues and gave vendors the opportunity to ask us questions and clarifications. We took questions that we could not answer and answered numerous ones of those on the website. Lots of questions on the terms of the contract and specifically how, detailed questions on operational issues of the program and questions for the vendor in filling out their application. However, we received numerous comments based upon all these comments we received, we decided to suspect bidding for the process on August 3rd. Bids were due August 5th, so this was before the bids were due to us. And consequently we're

also delaying the implementation of CAP until by July of next year. The statute allows us to do it. It says merely implement in 2006. So we will be still consistent with the statute. Just quickly to go over the revised implementation timeline, as I mentioned, the comments are still being accepted on the IFC until September 6th, and so far we've gotten numerous comments and they've been very useful. And I think as we're looking forward to more comments and being able to write a final Final Rule late in 2005, and hopefully clarifying and elaborating on some points that we had on the interim rule. Once we publish the Final Rule, we will have the bidding process reopened after that and sort of exact dates and timelines on that will be in the Final Rule, based upon that. We anticipate a 30- to 45-day bidding timeline. We'll also then have the physician election period that will follow for that. The election period will be as long as we can make it to make the July 1st deadline. The election period will be assuming we implement on July 1, July 1 through the balance of 2006. There will be another election period in the fall of 2006 for the entire calendar year in 2007, so it's sort of a bit of a trial period. We're posting a lot of information on our bidding website, and have been useful in trying to get information to vendors and physicians in addition to providing information through out physician and pharmacy Open Door list serve to try and communicate this because it has been very much of a real time process and things happening very fast. And so we have everything posted on our website. And also to clarify, we're putting a notice in the *Federal Register* with the correction notice and the suspension of bidding officially occurring. There were a couple of issues in the *Federal Register* that the weights were left off of the drugs. So we just want to clarify that so that everyone has that officially. I think that's the latest of where we stand on CAP.

Dr. Castellanos: Thank you Amy. We appreciate your being here. Are there any questions from the Council? Dr. Powers?

Dr. Powers: In the Final Rule, there are statements about leaving IVIG. And specific reasons for that, but it's not really clear, the reasons for leaving it out. I understand that it can be phased in.

Ms. Bassano: I think we just thought this time, given the comments we received, requesting it to be excluded. We want it to be excluded because there are various issues going on with it right now, and it was easier to leave it out but we would definitely be open to including it at a later date.

Dr. Powers: Who wanted to leave it out?

Ms. Bassano: I don't recall. I think there were various comments from manufacturers and beneficiary groups indicating that it should be excluded.

Dr. Grimm: It seems to be from your broad explanation of the suspension [off mike] there's going to be a lot of problems of the CAP program that are not resolved. Could you elucidate what the particular problems are? Is this an economic issue, what are the issues that are stopping this program from proceeding?

Ms. Bassano: I think vendors have concerns about their financial liability. We put clarifications on our website, one of the biggest concerns we were hearing was about the wastage policy, about how to bill for wasted drugs, that we had in the rule. We clarified that in our website that they can be consistent with the current policy because in the rule, we had taken a little narrower interpretation. But we clarified on our website last week, a week and a half ago that the billing should be consistent whether it's in the current ASP. If the vial size, [inaudible] higher vials, you don't use it. So I think that is sort of concern there. There's also concern about the co-insurance. About the collection of the co-insurance, that vendors are concerned about their ability to collect the co-insurance.

Dr. Grimm: Do you see this as a fundamental problem, is this program going to be economically sound for the vendors? My concern is that there's something more fundamental here. That these are just small, these are issues that seems to be resolvable, but there seems to be a larger issue that's looming here that this is not a program that's going to be able to be economically viable for vendors.

Ms. Bassano: I can't speak for the vendors, but just based upon these are the issues that they've brought to us, saying if you can help us with these issues it would help our financial ability to participate in the program. So we can only go based upon what they're telling us. Not knowing their bottom line or really how they're working, if they've told us this about the waste issue being a very big issue, then that's the issue.

Dr. Grimm: Did you have any vendors bid?

Ms. Bassano: We received no bids, although we did not expect any bids. We had a very short bidding time—accept any bids by the time we suspended the bidding. The bids were due 5:00 pm on August 5th. We had 30 days to bid. They had a lot of information they submitted to us. So we were

expecting that people were going to be running in at 4:59 up to our Baltimore offices presenting it to us then, given all the information that we were requesting from them in the relatively short period of time.

Dr. Grimm: Do you have any idea how many vendors will actually be in this game to participate? Do you have any idea how many will be submitting bids?

Ms. Bassano: I have no idea. It depends upon, I think the Final Rule. That's why we're very interested in seeing the comments to it. We did do a request for information back before the Propose Rule, and I think there were 11 or 14 interested parties who submitted comments to that. But that was much earlier on before we had even proposed the Proposed Rule. So we haven't really done anything like that. And we had a hundred and something parties, duplicative of the vendor conference call. So there is a fair amount of interest.

Dr. McAneny: First of all, I think that, I did read that Interim Final Rule, and I think that I don't' envy your job of trying to come up with a viable program, given the restraints that the legislation puts upon you, so you have my heartfelt sympathy on this one. But one of my major concerns, and I know it was one of the vendors' concerns from a different side is the fact that after they establish the process, attempt to do a co-pay, attempt to set up a payment plan, the problem is that in cancer patients, and a lot of this is aimed at cancer patients, when they're not working, they're busy getting treatment, there is no money. There is no way that they're going to be able to make that co-pay. Physicians have traditionally gone through the steps that we are required to go through by law to attempt to collect those co-pays, but we know that we're going to end up eating it when the patient doesn't have it. And we continue to treat those patients because when you're looking at a patient face to face, and saying I know you have a curable lymphoma, so we're going to continue to treat you. Or even if you have something that you're just palliating, with the provision in there that the vendors can cut somebody off 15 days after they fail to make their plans, or that the vendors can then appeal to 501C3 organizations to then pay money back to this corporation? That's sort of a separate issue, but that to me seems inappropriate, that a 501(c)3 that I might donate money to in good faith thinking I'm helping a patient then goes to a corporation to keep them profitable so they'll stay in the business. I think that's inappropriate. But my plea is that it is just unfair to the patients that an executive of a vendor corporation can make the decision to cut somebody off and they never have to face that person face to face and say I'm sorry, you get to die now. But when I'm in my practice, looking at that person, that's what it

will come down to and the person that they will see will be me. So my plea and my recommendation that would come out of that is that the CAP vendors not be allowed to discontinue provision of chemotherapy drugs to a patient, regardless of the patient's ability to pay the co-pays. And I'd make that as a formal recommendation.

Dr. Castellanos: Is there any discussion on that motion?

Ms. Bassano: Just a clarifying comment. The Medicare supplier provider agreements do not require services to be provided except in cases of emergency and civil rights, so just to clarify. That's what we were coming up against, that the Medicare requirements do not require that suppliers continue to provide, it's at their option.

Dr. Castellanos: I know we have a motion on the floor. But as part of your presentation, you mentioned that the vendor could waive this if the followed the IG rules to suspend. What are the IG rules to suspend?

Ms. Bassano: My understanding is that the IG will allow you to waive the co-insurances if the provider's made an attempt to collect it. If there is a demonstrated financial hardship and that they're not advertising this and they're not doing it on a regular basis so they're not saying come to my practice or come use this vendor because I never will collect your co-insurance. So if it's on a case by case basis, it's not routine, and that there is a demonstrated hardship.

Dr. Castellanos: Does anybody review that?

Ms. Bassano: I think the IG.

Dr. Castellanos: Do they actually have a policy where they're going to review each one?

Ms. Bassano: I don't think so. But I don't know how they audit that.

Dr. Castellanos: Well, you know, that's what happens in our practice. Each person is very, very important. That's somebody's mother, father, brother sister. When making that decision, I have that decision like Barbara does in my practice. And right now, I'm eating it because I have a moral and legal and ethical and whatever obligation you want to put, but when the CAP person who's sitting up in Washington or wherever in a big shiny building, he doesn't see that person eye to eye. That's going to be a big problem.

Dr. McAneny: Another point to that same issue is if I'm treating someone with a planned course of therapy, and they do not make their co-pays, and the vendor makes the decision, we've tried X, Y, and Z and we're cutting them off, and I then get to go back to that patient and say I'm sorry, you're cut off. I can, that's abandonment, as well. And so that puts the physician really in an untenable moral and ethical bind. Our only option, according to the Interim Final Rule is to then opt out of the CAP program. So for each patient that this comes up, our only option is to opt out of CAP. Which means essentially that my only option as a provider is to say I will opt out of CAP, and in order to not commit abandonment with both the legal and the ethical implications of that, is to say, I will now eat the 20% co-pay that you can't make. I will continue to purchase for you on the ASP plus 6 market these drugs, and get essentially 86% of the cost of the drug and chew up the rest. So that's the only option that we are given. I would submit that the vendors, since they tend to be large, nationwide, pharmaceutical distributing corporations have a slightly greater ability to eat that cost than I do as a physician in my practice. So I would hope we pass this recommendation, but I would also hope that you would hear not to put me in this untenable situation.

Dr. Castellanos: Are there any other comments on that motion? Dana could you repeat that please for us?

Ms. Trevas: The Panel recommends that CMS not allow CAP vendors to discontinue provision of chemotherapy to a patient regardless of the patient's ability to pay his co-pays.

Dr. Przyblski: I don't know what's on the CAP list. Chemotherapeutic drugs seems somewhat restrictive and I don't know if there are other examples outside of chemotherapy where it would seem unethical to just discontinue it. So I would suggest a friendly amendment that maybe too—

Dr. McAneny: Incident to would work.

Dr. Castellanos: Incident to drugs.

Dr. McAneny: Or the drugs covered under the CAP.

Dr. Castellanos: There are 180 drugs that are covered under CAP.

Dr. McAneny: I'd consider that a very friendly amendment, so we'd just change it to provision of drugs covered under the CAP to a patient. Would that be?

Dr. Castellanos: Is that acceptable?

Dr. McAneny: Are there any other discussion on this motion. Dana, I'd appreciate if you could repeat that please.

Ms. Trevas: The Panel recommends that CMS not allow CAP vendors to discontinue provision of drugs covered under the CAP to patients, regardless of the patient's ability to meet co-pays.

Dr. Castellanos: All in favor?

[Ayes]

Dr. Castellanos: Opposed? Are there any other—Dr. Grimm?

Dr. Grimm: There was one concern about this issue of participation I'd like you to explain in terms of group participation versus an individual participation. So I'm concerned, a number of our constituents are concerned about the fact that if one person is participates in CAP, the whole group has to [inaudible]. I'd like you to clarify that for us.

Ms. Bassano: Sure. That is the requirement. That the group elects to participate in CAP, at the group level. It's not at a individual physician level. It's the entire practice is electing to participate in CAP. There are some requirements though that if a physician has a separate ID number and has a separate practice in addition to the group practice, they could elect through that practice. But it's at the individual practice level, so the entire group, is electing into the CAP program.

Dr. Grimm: There's certainly some concern on physicians that that can be unfair to individual physicians that don't want to participate in the CAP. Because some of our groups are—we are multi-specialty groups, of which we don't all have the same criteria in terms of how we practice and the issues involved and that we're all going to get, we're going to have to submit to participation simply because of this rule. I would like to make a recommendation if I may, for PPAC recommends that CAP participation should be on an individual basis, and not as a group requirement.

Dr. Castellanos: Is there any discussion on that motion? Just a point, that this is the only policy under CMS where it requires, there's a distinction between an individual and group. This is the only policy that CMS has where an individual determines whether the group participates or not. I'll call the question. All in favor?

[Ayes]

Dr. Castellanos: Opposed? Are there any other? Gerry?

Dr. O'Shea: We've had some discussion about including the calculation of the ASP and we feel as a group that it's kind of inappropriate, so I'd like to make a recommendation also, please.

Dr. Castellanos: Fine, Dr. O'Shea?

Dr. O'Shea: PPAC recommends that CMS remove CAP vendor prices in the calculation of the ASP. We feel that the inclusion is duplicative and unfair to physicians electing not to participate in CAP.

Dr. Castellanos: Is there any discussion on that motion?

Dr. Przyblski: Did CMS not respond somewhere in one of the documents that we've gotten that they are not able to do that because it's not on the list of exclusions?

Ms. Bassano: We did say in that rule, but there, our lawyers now believe there's a legal authority for us to exclude from ASP because the law specifically has exclusions and this is not one of them. So we responded to those comments in the Interim Final Rule.

Dr. Przyblski: So the mechanism would then be to change the law that would add that to the exclusion.

Ms. Bassano: Right, we're also open to alternative legal approaches and theories. So if we receive that as a comment, to the rule, we're open to alternatives.

Dr. Castellanos: I think we talked about it, Amy, and I know I talked to Herb and Ken about this. I'd like to make a motion that CMS—OK, there is a motion on the floor. I'm sorry. I guess it really is—we can prove it, but it's already been answered this morning earlier. It was the same motion.

Dr. McAneny: Actually on that, because I thought there was some discussion whether or not that was truly Representative Thomas's intention when he wrote this whole program, because he's been quoted in various publications, *Insider News*, and others that says it was not his intention to have the ASP from the CAP program contributing to the calculation of ASP for people who are not participating. So maybe the motion could switch to.

Dr. Castellanos: We have a motion on the floor. Can I make a friendly amendment to that?

Dr. O'Shea: Yes.

Dr. Castellanos: I recommend that PPAC recommends that CMS work with Chairman Bill Thomas of the House Ways & Means Committee to clarify how Congress intended the ASP and CAP to function independently of each other.

Dr. O'Shea: And Ron, I think that we can just add that onto my motion as a last sentence, and then it's all inclusive. I think that we can just add that to the motion that was already on the floor. I'd like it to be inclusionary, what he said, not to replace it, please.

Dr. Castellanos: Dana, could you read that back for us please?

Ms. Trevas: The Panel recommends that CMS remove CAP vendor prices from the calculation—or

Dr. O'Shea: In the calculation?

Ms. Trevas: In the calculation of average sales price. The inclusion is duplicative and unfair to physicians not participating in CAP. The Panel further recommends that CMS work with Chairman Bill Thomas of the House Ways & Means Committee to clarify how Congress intended ASP and CAP to function independently of each other.

Dr. Castellanos: How CAP and ASP can function independently of each other. Could you read that again—and let me just make sure. I wasn't sure what you said.

Ms. Trevas: The Panel recommends that CMS remove CAP vendor prices in the calculation of average sales price. The inclusion is duplicative and unfair to physicians not participating in CAP. The Panel further recommends that CMS work with Chairman Bill Thomas of the House Ways & Means Committee to clarify how Congress intended ASP and CAP to function independently of each other.

Dr. Castellanos: Is there any question on that motion. Dr. Urata?

Dr. Urata: It seems to me that we should just separate those two and just have two different motions. They're requesting two different things. It would be simpler and clearer and more directive if they're two separate motions.

Dr. Castellanos: Could we go one motion at a time. We'll do Dr. O'Shea's motion first.

Ms. Trevas: The Panel recommends that CMS remove CAP vendor prices in the calculation of average sales price. The inclusion is duplicative and unfair to physicians not participating in CAP.

Dr. Castellanos: Is there any further discussion on that? I'll call question, all in favor?

[Ayes]

Dr. Castellanos: Opposed? Could we go to the next motion?

Ms. Trevas: The Panel recommends that CMS work with Chairman Bill Thomas of the House Ways & Means Committee to clarify how Congress intended ASP and CAP to function independently of each other.

Dr. Castellanos: Is there any question on that motion? All in favor?

[Ayes]

Dr. Castellanos: Opposed? Are there any other? Dr. McAneny?

Dr. McAneny: Looking at the, I have a couple and then two recommendations. The Interim Final Rule is felt that there would not be an administrative burden on physicians who participated in the CAP program, yet Medicare is not all of our practice, therefore, we are required to still continue with the buy and bill and to maintain an inventory of drugs, which we can do by bulk purchasing and then just sending out one bill with administration and the drug on that bill for private payers. Yet if we participated in CAP, we then have to, even though it can sit on the same shelf with our stock, we still have to maintain a separate inventory calculation, how much is stock that's available for the general population, and how much is stock available for Mrs. Jones under the Program. And we then have to get that prescription number, make sure we have that, put the prescription number on the claim when we submit the administrative claim which goes to one carrier. We have to make sure we have the prescription number when we send that information back to the vendor. We have to have that prescription number on that to notify the vendor that the drug was indeed given within the one-week period allowed, and then if there's, we then provide the vendor with all of the necessary information to file the secondary insurance if there is one, help with appeals, etc., etc., so it's my opinion that really is significant amount of administrative burden that being part of the CAP program will put upon a physician. So I would like to make a recommendation about that, which is that PPAC recommends that CMS reevaluate its contention that working with the CAP vendors will not increase the administrative burden on physicians as all of the things I just described, as filing prescriptions with the vendor, I've got it I can copy it to you, filing administrative claims without the drugs attached, but with a prescription number, helping vendors with billing information and keeping separate inventories for CAP patients is far more work than buying in bulk and submitting one bill which contains both the administrative codes and the drugs.

Dr. Castellanos: Do you want to do that again, Dana?

Dr. McAneny: I'm asking that CMS reevaluate the contention and the fact that they did not include any administrative fees for the physician in dealing with the CAP Program.

Dr. Castellanos: Is there any discussion on that? I think it is a little ironic that CMS recognizes this fee for pharmacists, and they do pay the pharmacists for dispensing and costs related to this, but when it comes to the physician there's no ability to do that, there's no will to do that.

Ms. Bassano: Can't speak to the Part D, but my understanding is that there is specific requirements in the law on that side, that are, using our discretion on the CAP side, we thought that based upon the comments that we received, that the admin burden would be equivalent between ASP or CAP. But we're happy to look at the issue again.

Dr. Castellanos: Dana, could you read that motion please?

Dr. McAneny: Would you like me to read that motion? [laughter]

Ms. Trevas: [off mike] The Panel recommends that CMS reevaluate its contention that working with CAP vendors will not increase the administrative burden of physicians. Is that OK?

Dr. Castellanos: Is there any further discussion on that motion? All in favor?

[Ayes]

Dr. Castellanos: Opposed?

Dr. Grimm: Would that suggest that we're asking them to report at the next meeting? I mean just asking to reevaluate it with no timeframe on it is kind of open-ended.

Ms. Bassano: The comments, the recommendations, become comments to the Final Rule, so we would respond to it in the Rule.

Dr. McAneny: And finally I'd like to recommend that CMS has recognized the increased cost of dispensing drugs by pharmacies, and added an additional 2% for pharmacy costs and hospitals for distributions for these drugs, even under the ASP plus 6, that CMS treat physicians equitably and add 2% more to ASP plus 6 for physician offices not participating in the CAP and add a dispensing fee for physicians using the CAP.

Dr. Castellanos: Is there any question on that? Amy, could you repeat that motion, please?

Dr. McAneny: You're making Amy do it? [laughter]

Ms. Bassano: No. [laughter]

Dr. Castellanos: Dana, excuse me.

Ms. Trevas: Given that CMS has recognized the increased cost of dispensing by pharmacists and added 2% for pharmacy overhead under the ASP plus 6% formula, the Panel recommends that CMS treat physicians equitably and add 2% for physicians not using the CAP, and add a dispensing fee—

Dr. McAneny: 2% more to ASP plus 6, like they're doing in the hospital outpatient.

Ms. Trevas: OK. And a dispensing fee for physician not using CAP.

Dr. McAneny: No, a dispensing fee for physicians using the CAP. And the ASP plus 6 system gets an additional 2% for, like the pharmacies and the hospitals do.

Ms. Trevas: OK. The whole thing?

Dr. Castellanos: Please.

Ms. Trevas: Given that CMS has recognized the increased costs of dispensing drugs by pharmacists and added 2% for pharmacy overhead under the ASP plus 6% formula, the Panel recommends that CMS treat physicians equitably and add 2% for physicians using the ASP plus 6% formula and a dispensing fee for physicians using the CAP.

Dr. Castellanos: Is there any further discussion on that motion? Call the question. All in favor?

[Ayes]

Dr. Castellanos: Opposed? Are there any other questions for Amy? Thank you. We appreciate your being here again, and look forward to hearing these answers.

Dr. McAneny: And good luck. [laughter]

Dr. Castellanos: Believe it or not, we're still on time.

PRIT Update

Dr. Castellanos: It's our privilege and pleasure again to have Dr. William Rogers talking about the PRIT Update. As most of you know, Dr. Rogers is the Medical Officer to CMS Administrator, Dr. Mark McClellan. Dr. Rogers will provide us an update on the Physician Regulatory Issues Team or better known as PRIT.

Dr. Rogers: Thanks Ron, I'm pleased to be here again. At the last meeting, I was down in Florida speaking to urologists, and I just couldn't get out of that, or else Dr. Castellanos would have never forgiven me. So, but it's good to be back. Herb missed the Code of Hammurabi and I wish that you had all seen his

face when Dr. McAneny congratulated Dr. Hunt on having both his hands. I think that exactly what she was saying was a little bit lost on him. But it was a pretty funny expression. I want to just do quickly a little bit of follow up on Jeff's presentation earlier today about the Part D benefit and the impact on physician offices, and we're in the Office of External Affairs and a couple of other offices in CMS doing everything we can to make sure that physicians are not burdened by the patients' requests for information and help with filling out forms and things like that. And I think you'll all be deluged over the next few weeks with information about that. We talked to AMA and other physician specialty societies and they pretty much all agreed that probably this was the appropriate time to talk to physicians about the Part D benefit. That if we'd done it any earlier, people would have been less interested. Also, PhARMA is helping with outreach. The detailers are going to be bringing information into your offices when they come in to do their normal detailing. And they've been very helpful with us.

I'm going to talk a little bit about the issues that you'd asked us to look at in the last meeting, although Ken sort of stole my thunder in reporting on the outcomes of those. And then we'll talk a little bit about the PRIT issues. But of course, as you know, this is my personal contribution to the meeting. Is always to have a cartoon or too in my presentation. The half level payment, as Ken mentioned, created a problem with the cert error rate, and so I think that issue is going to disappear. It turned out to be very laborious for the carriers to implement and the cert error rate probably was the final straw. ASP underwater drugs. We've continued to make ourselves available to providers asking them to let us know about drugs that they're having trouble acquiring, and what we've done as we have heard about these drugs is we have passed them on to Amy's group. We've tried to get them as much background information as we could about what the prices were sort of in the market and we've had some notable successes. One manufacturer is producing an ophthalmologic drug found out after reassuring us that they had not made a mistake that they actually had made a mistake on calculation of ASP and the new ASP is actually $360 higher than what the old ASP had been. We've had other corrections which have been smaller, but that was an example of how important it is for providers to let us know when they're seeing a gap between our ASP and what they're seeing in the market. This was an issue that Dr. Senagore particularly had brought up to us. It was the issue about whether it was fair to ask physicians to put down the time and date of their notes when they were operating in their office but their office was within a hospital. And he felt that that was a lot more

work than necessary and probably wasn't reflective of doctors' practices when they were working in an office which wasn't part of a hospital. This is required by our Conditions of Participation. And in discussion with physicians within CMS and outside, I think probably most of us believe that putting a time and date takes so little time and is such a good practice that is probably not something that we would consider burdensome, and my own experience, running emergency departments is if you tell doctors well, you know, do this on Tuesdays and Wednesday and Fridays, but don't do it on Mondays and Saturdays and Sundays, it ends up not getting done at all. So I think probably it's a good practice for all of us. I know I try to put times and dates down any time I put a note or an order on a chart, and the only way I can do it consistently is if I sort of do it every time I write a note.

Tom Gustafson wanted me to put this in. [laughter] Talk about a few of the issues that we've been working on. The format of the Remittance Notice. A group practice, which was using the information on the Remittance Notice to divide their PSA bonuses up amongst their physicians had trouble because of the format of the Remittance Notice. And so actually CMS is now preparing to release software, which will allow your office managers to take the data that's in the Remittance Notice and convert it into an Excel spreadsheet and do lots of different manipulations with it. So when this software is available, your office managers will be able to take that data and slice it and dice it in ways that are appropriate to your practice. I was pretty excited about that. I think that's a great solution to that problem.

Use of macros in teaching documentation. This has been a long drawn out issue that we've been working on for a long time, but I think that we now have achieved some consensus about what the policy should be and the feeling is that this is such an important issue that clarification of the policy should probably be in the manual so that's what we're working on now.

The CPT-36476 and 479 was brought to us by people coding surgical procedures, and this has to do with the multiple surgery indicators and I'm not going to go into the details but we're working on a resolution to this and I think the outcome's going to be good.

CME has been a problem. There are stark concerns about the value of CME provided by hospitals to members of their medical staff. And the AMA wrote a letter to Dr. McClellan expressing their concerns. And the response to that letter, which I think be very helpful to all of us is going to be released pretty soon.

Electronic resubmission of claims, denied claims. This is an interesting issue. Because of concerns about fraudulent billers, who might just use the efficiency of the electronic system to continue to submit claims that had been denied until they finally cleared whatever hurdle it was that had been thrown in their path and got paid, led us to suggest maybe policy to require denied claims be resubmitted on paper rather than electronically. But that creates certain problems, so we've helped to develop a dialog between our policy staff and people on the outside with expertise in this issue and we're looking for a policy which will better serve both sides of this issue.

H&Ps for outpatient surgical procedures. There was some surgeons who particularly are operating at sort of magnet hospitals, surgeons that patients are willing to travel a great distance to see, have been asking their patients' primary care physicians to do H&Ps and send the H&Ps in with the patient. So that the surgeon can use that document to meet the requirement that patients have an ambulatory surgical procedure have and H&P on the chart. But our Conditions of Participation say that if you do something in the hospital, you have to have privileges at the hospital, and so you would really need to be privileged to write an H&P, which would meet the requirements. And we have had discussions with the American College of Physicians, the American College of Surgeons, about this issue and I think the consensus is among surgeons is that probably best practice is when a surgeon is going to do an operation on a patient that the surgeon do the focused H&P. There's time in the value that was assigned by the RUC to the surgical procedure, about an hour of time for pre-surgical services, and that should be included in this. So the expectation would be that for patients who were pretty healthy, that this H&P actually be done by the surgeon who's going to be doing the procedure. However, of course, a patient who has significant co-morbid conditions, a bad COPD, or pulmonary emboli, a bad thrombophlebitis. might need to have an evaluation by the appropriate medical specialists, or general internist or family physician, prior to the procedure, and that should be payable in those circumstances, and that physician would be a credentialed member of the medical staff, would be able to step in and help out, if the co-morbid condition did present a problem after the surgical procedure. So it's been an education for us. We didn't realize that so many physicians, internists and family physicians, were being asked to do these H&Ps for the surgeons.

Dr. Urata: When I do this, on a patient who's flying to Seattle in a week or so to have surgery, they're basically stable, I'm pretty sure that the surgeons are doing a focused H&P and they just want a

medical. But for my patient then to add and have to see somebody he's never seen before at that facility to do a general medical exam doesn't make sense.

Dr. Rogers: No, you're absolutely right, and that's not the intention. The intention would be that the surgeon does a focused H&P, attaches that H&P to the chart, and that meets the requirements.

Dr. Urata: In some cases, I would recommend that patients see a cardiologist prior to surgery and then we have to change plane tickets and all that kind of stuff.

Dr. Rogers: Right. No I think your practice is a good practice, but on the other hand you shouldn't feel obligated to do a comprehensive H&P for the surgeon.

Dr. Urata: Well I don't mind it because I'm the one that has the thick chart, access to the thick chart and I've seen this patient for years, and I think that's appropriate to do that.

Dr. Rogers: I think your practice is the optimal practice.

Dr. Urata: But I don't have credentials at the other place.

Dr. Rogers: Right, and that's why the surgeon would have to do an H&P. The H&P on the chart would have to be from the surgeon that was from the hospital—

Dr. Urata: OK, then that would satisfy Medicare rules. That's correct.

Dr. Sprang: Don't you think it's going to be a conflict with some hospitals. Because my hospital they have a whole series of elements of what needs to be on the H&P by whoever puts it in there. And right now, we often have primary care physician do it.

Dr. Urata: I actually get a blank sheet of paper, I mean a sheet of paper with those requirements on there and what labs to do, depending on what age, and all that sort of stuff.

Dr. Sprang: But that would be on yours, but not on the surgeons. And it seems like there's some conflict there as to what would be acceptable in the hospital.

Dr. Rogers: Well, normally an ASC in my experience, there is an H&P form that you can use that is more abbreviated than for a complicated ICU patient who's being admitted, but you know, if you have a hospital policy which makes it burdensome for the surgeon, then I'd go through the medical executive and maybe look into changing that policy. Because I don't think it's probably necessary for someone who's having a bunionectomy to have a very, very comprehensive and detailed H&P just to meet the requirements of the ASP.

Dr. Sprang: [off mike] medical records, which we are totally on, they want all the boxes checked off, and it is going to be more burdensome.

Dr. McAneny: Then you can just email it to the hospital.

Dr. O'Shea: I'm in agreement with Dr. Urata here. As an internist, I do some pre-op evaluations and it truly is to asses risk factors prior to surgery for some specialty hospitals in San Francisco that I'm sending my people to. I'm not going to have privileges there, but they're looking for me as the primary care to release them. I think there's some conflict there. But you're just saying that that can still be done and I can still bill for it, but you want something more comprehensive from the surgeon who's going to perform it also.

Dr. Rogers: Well, the thing that would be required by the Conditions of Participation would probably be less extensive than what you're doing. But there is a requirement that the patient have an H&P on the chart, and the H&P has to be done by a physician who is credentialed.

Dr. O'Shea: At that hospital.

Dr. Rogers: At that hospital. So that requirement would have to be filled by the surgeon. We do not say how many pages long the H&P has to be, and one would hope that—and then the information that you sent would be background medical information that certainly could be included into the chart, but it wouldn't meet the Conditions of Participation requirement for the H&P.

Dr. Simon: [off mike] doesn't have that requirement on either. What they do require is that the appropriate information be provided in that medical record for whatever procedure it is that patient's going to undergo. So it really would be patient specific. And there are no hard and set rules that it has to be a comprehensive or X number of pages, what have you.

Dr. Przyblski: In principle, I agree with the surgeon at least documenting some form of history of physical. I do want to clarify though a statement that you made about 60 minutes of time already being accounted by the RUC to do that sort of work. And that number may be true for some codes, but it's certainly not universal. There's a been a lot of debate at the RUC as to whether the pre-operative H&P is or is not included in those services. I'm just looking at the RUC data base at a couple of services where pre-service time is 19 minutes and that's talking to the patient about the procedure that they're undergoing, the

risks, the benefits, and signing surgical consent, and doing an H&P all in 19 minutes is probably unrealistic, so it may be true for some codes, but I just wanted for the record that that's not universally accurate.

Dr. Rogers: No, you're absolutely right. And we went to the RUC database, too, and looked up that and it is frustrating is that there is some inconsistency there.

Dr. Iglar: Since there aren't any orthopedists on our committee, I don't even know if somebody's going in for a hip procedure at another hospital whether an orthopedists has a stethoscope [in his pants?] [laughter]

Dr. Rogers: [off mike] put the stethoscope on the umbilicus and you can hear the heart in both lungs? [laughter] Payment for low osmolarity contrast material, this is fixed. It was fixed on July 29th. I'm sorry the slides a little dated because I had to submit these early.

Dr. McAneny: So it's paid for now?

Dr. Rogers: Yes, paid for. RV is pediatric codes. The pediatricians asked CMS to list the RVUs for codes that CMS didn't pay for. That's helpful for them because so many of the other payers just use sort of the physician rule as their template. And so we batted about 99%. We got all of the codes in there that they wanted with 2 exceptions that we missed. But I think the responsiveness was something that they were pleased to see.

ASP problems we've just talked about, Amy talked about at some length. And the Recovery Audit Contracts. We are still reminding physicians when we speak to them all over the country that we are very interested in hearing about any specific problems people are having. And frankly, we have not gotten any specific feedback from anybody yet.

Dr. Grimm: Do you think that's probably just a hospital thing, and not actually a physician—and that's probably why you're not hearing anything from physicians yet?

Dr. Rogers: Oh, right! Yes, we're not interested in hearing from hospitals. We're just interested in hearing from physicians.

Dr. Grimm: But this is focused on hospitals. So far.

Dr. Rogers: So far. Right. No we're hearing concerns but nobody's had any experiences yet. Competitive Acquisition program we just talked about, the co-signature requirement has been fixed. This

had to do with critical access hospitals. And ordering of POVs. This is Dr. Urata's issue. And I think that the outcome is going to be very gratifying.

Dr. Grimm: What does that mean, though?

Dr. Rogers: I can't say. [laughter] Ask Herb. And in cardiac rehab supervision, on June 29th, Office of coverage opened a national coverage decision on cardiac rehab supervision, so I'm hoping that comments will be helpful and we'll get a policy which allows, particularly the rural hospitals to offer this service. And this is a little dated too, but some of our upcoming speaking engagements. I don't know why October was so quiet. So I look forward to hearing from you all, the new members of the committee that I haven't met before. Those are my phone number and email address.

Dr. Castellanos: Bill, I have a question on electronic resubmission of denied claims. It's really a two-way street. In Florida, there is a glitch put in by the carrier, where all LHRH drugs were denied in July. And any claim that was submitted, we have to now answer by payback in work, in a paper form, even though it was there problem. And the real problem there is, Jim did a good job, our carrier medical director. They let everybody know. He said, look, don't submit any more claims until we got it cleared up, and that's what most of us did. But we still have a backload of claims because we're doing this on a daily basis, that we have to now answer in paper form which takes a lot of work. So it's a two-way street. It's not always the person putting in the claim. It can be the carrier also.

Dr. Grimm: Can I make another comment on that, too? The argument that this shouldn't be allowed to be done re-electronically submitted. The fact that's somebody's going to abuse this doesn't seem to me to hold water in terms of a rationale. Because anyone who's looking and saw 8 claims come through electronically could immediately say someone's abusing this. And if there's one issue on electronic form that's wrong, there should be a way just to correct that and send it back in. And it just as we've mentioned, doing the re-paper stuff is tremendously burdensome. Especially when it's like one item on the electronic form that's incorrect, like a number or a dash or something strange like that. So I would really go back to that issue. I really think that's a really weak argument for not allowing re-use of the electronic filing.

Dr. Rogers: If PPAC wants to make a resolution on that, that's fine.

Dr. Urata: Make a recommendation Peter. I'll second it for you. [laughter] And you can use my pen, too.

Dr. Grimm: I will draw it up and make it a resolution after lunch. Do you want me to do that?

Dr. Castellanos: Good! We'll do that after lunch. Bill, we always appreciate your comments and your cartoons [laughter] We'll look forward to your next meeting. Actually we're going to break for lunch now. We'll reconvene at 1:00. Lunch for Council members is in room 505. Excuse me we have one comment.

Dr. Simon: Just wanted to state that in February, we will have four Council members coming off the Council. We have published in the *Federal Register* the nomination process for eligible and interested individuals for the PPAC. And so the comment period ends, I believe, the 16th of September, so I refer you to the *Federal Register* notice, so that for those interested parties, they can obtain the appropriate information and submit applications for nominations.

Dr. Castellanos: Are there any other comments? Good, we'll see you back at 1:00. Thank you.

Lunch

Swearing in of New Member

Mr. Kuhn: To start out this morning, we have one new member of PPAC, Dr. Leroy Sprang. And Leslie Norwalk, our Deputy, our Deputy Administrator, is joining us for the first part of the session this afternoon and she is going to administer the oath and swear Dr. Sprang in. So I'll turn it over to Leslie.

Ms. Norwalk: Dr. Sprang? Nice photograph. Raise your right hand, put your left hand on the bible. Repeat after me. I LeRoy Sprang.

Dr. Sprang: I LeRoy Sprang.

Ms. Norwalk: Do solemnly swear.

Dr. Sprang: Do solemnly swear.

Ms. Nowalk: That I will support and defend

Dr. Sprang: That I will support and defend

Ms. Norwalk: The Constitution of the United States

Dr. Sprang: The Constitution of the United States

Ms. Nowalk: Against all enemies, foreign and domestic

Dr. Sprang: Against all enemies foreign and domestic.

Ms. Norwalk: That I will bear true faith and allegiance to the same

Dr. Sprang: That I will bear true faith and allegiance to the same

Ms. Norwalk: That I take this obligation freely

Dr. Sprang: That I take this obligation freely

Ms. Norwalk: Without any mental reservation or purpose of evasion

Dr. Sprang: Without any mental reservation or purpose of evasion

Ms. Norwalk: And that I will well and faithfully discharge

Dr. Sprang: And that I will well and faithfully discharge

Ms. Norwalk: The duties of the office

Dr. Sprang: The dues of the office

Ms. Norwalk: On which I am about to enter

Dr. Sprang: On which I am about to enter

Ms. Norwalk: So help me God.

Dr. Sprang: So help me God.

Ms. Norwalk: Congratulations.

Dr. Sprang: Thank you.

[applause]

[chat]

Mr. Kuhn: All right, again, good afternoon everybody and welcome back to this afternoon's session. As I stated earlier, Leslie Norwalk, our Deputy Administrator is here with us this afternoon. And we're thrilled that Leslie could be here to not only swear in our newest member of PPAC but also be here an opportunity to make a few remarks about the activities she sees at the Administration of the Agency. And I have to tell you, and I think that's no surprise to anyone, that this Agency, under the leadership of Dr. McClellan and Leslie Norwalk is in terrific hands. And I think the effort to move forward, not only in the MMA but the other activities that the Agency is engaged in, we're meeting our milestones. We're making things work. We're doing more outreach than ever before. And I think it's a real tribute to Mark and

Leslie's leadership, and so with that, let me hand it over to Leslie just for a remarks and then committee can ask her a few questions and we'll proceed with our agenda this afternoon.

Ms. Norwalk: Well, first thank you all for participating in PPAC. I suspect that you can never hear that enough. But we really do appreciate hearing from people who are actually practicing. I know that when I spoke with friends from the AMA, they're delighted that we actually have a doctor at the head of the agency and I can assure you that Mark spends a fair amount of time in his role as administrator, remembering what it was like to be an internist, so you are really well represented at the top of the organization. But that's not to say we don't totally appreciate the amount of time and effort you spend on a quarterly basis with us in going over the issues, whatever they may be, in terms of giving us a perspective that's very real life. I think that's critically important. In fact, one of the reasons I started at CMS almost 4 years ago, was I'm an attorney by training, and the head of my law firm said Leslie, they could really use some people at CMS who really knows what's going on in the real world. And who's spent time with all of the different provider types, which, I had a fairly broad base of clients. And I think that now that I'm in the little glass house that is CMS and looking to the outside, we often forget, so it's really important to have advisory committees, and access to the real world and what happens and we do and how it impacts the real world. And that's the role that I think you all play and I greatly appreciate that, in fact, all of us at CMS doe. So thank you very much for your service.

Most of my time these days has been spent implementing the Medicare Modernization Act. And in particular the drug benefit. I know that Dr. Kelman spoke this morning about the MMA, but I thought I would give you my perspective of being on the road and knowing how important physicians will be, because just by the sheer nature of beneficiaries asking you what you think about something. So let me give you my 13 points about the Medicare Drug Benefit, that I divide into 5, 5, and 3, as I call it. So it's a way for me to remember whenever I'm talking to people, some of the key tenets. The first five is the five reasons why or the five things that were important when the MMA was being debated and before it was passed, why it is that we have this Medicare Modernization Act, why the drug benefit is important or what were the goals we were trying to achieve. The first one is that it be voluntary. That's one of the reasons why the physician component is so important because beneficiaries I have no doubt will be asking their physicians all over the country, should I do this? Shouldn't I do this? So on and so forth. And it's voluntary

for those who are 65 and over, voluntary for those who are on Medicare because of a disability, or ESRD, and it doesn't matter whether or not you have a preexisting condition and so on and so forth. It's great that it's voluntary. I think that we learned after the Catastrophic Act was repealed in the early '90s that the voluntary nature of this benefit was going to be very important. But it does give CMS significantly greater burden in making sure that the 42 million Medicare Beneficiaries that we have an opportunity to enroll and actually learn about it so that they can take advantage of the coverage. So voluntary is the first part. The second part is catastrophic coverage. And I'm quite sure I don't have to tell any of you the importance of catastrophic coverage a day and age where you've got drugs like Gleevec to help put leukemia in remission for however long it can at $40,000 a year. Other drugs for rheumatoid arthritis and so on and so forth that can be incredibly expensive that Medicare currently doesn't cover, and yet it can provide tremendous advantages to patients, in particular, keeping them out of other treatment facilities, or frankly keeping them alive. At the same time, we can keep someone alive, we can absolutely scare a family to death. What do we do about a bill that is so large in terms of constantly paying it to keep the medications that are needed? When I was in Florida earlier this year, I did a town hall meeting and to illustrate this point, a gentleman came up to me and said, Leslie I've been married to 50 years, I'm really fortunate my wife and I are covered under an employer policy because I'm retired in my company continues to provide drugs. She does have leukemia and she's on Gleevec, and I'm really, really worried that my employer is going to drop the drug benefit that it has because they have been frankly over the past 15 20 years, employers and unions alike have been dropping their employer retiree plans pretty significantly. In 1988, it was 66% of all large employers. Now it's in the mid 30s in terms of those that offer. He was very worried he would be among them. When I told him that the drug benefit would cover Gleevec, starting in 2006 and beyond, he was delighted to know that in fact, he was not going to have to choose between keeping his wife alive and living in the same house they've lived in for year. So I think that is very important, coverage is important for a number of reasons. It doesn't frankly matter, well maybe if you're Warren Buffet, you don't care, but anyone else, I feel quite sure forty grand is a nice chunk of change, and every year to have to pay that's frightening. So it is irrelevant to your income level that catastrophic coverage is available. So even Warren Buffet, if he signed up for the benefit, could get it. However, so that's voluntary catastrophic. Third point is limited income. For those who need extra help because of their limited incomes, they will get it. With, and I

think that Dr. Kelman spoke of this earlier, but the point is basically 95 to 99% of their costs are covered. It's an insurance benefit, but those who are, that qualify don't pay a premium, or a very small premium depending on their income and resource levels. They don't have a coverage gap. They only pay very small co-payments. And this is critical of course because one of the groups that is counted in limited income are those who are dual eligible on Medicare and Medicaid. And the Medicaid beneficiaries will now be getting their coverage through Medicare if they're dually eligible. So voluntary, limited income, catastrophic, one other group is the employer group. Those who are retirees, who are fortunate enough to have coverage through an old employer or union, the Medicare Modernization Act actually provides a subsidy for those companies and unions that continue to provide retiree health plans. A subsidy's 28% of every dollar spent between $250 and $5000 per individual, provided that coverage is as good or better than the Medicare coverage. We are very hopeful that we will have significant number of employers and unions continuing to keep their retiree coverage. That's what beneficiaries want. If someone were to ask any of you, what should I do? The first question I almost always ask is well, do you have retiree coverage. And the answer is yes, are you happy with it? Do nothing. Look for something in the mail that says you have coverage that is as good or better than Medicare, the technical term is called creditable coverage, if they've got that, life is good. They can go on and not have to worry about a late enrollment penalty later or anything else. They can just simply continue their coverage as it is. Finally, of the 5 principles of the MMA is cost. If you read the papers in the end of 2003 and anytime frankly last year, you'd know that while the intent was keep the cost below $400 billion for the 10 years in which the Bill was passed in terms of that budget window. When we announced the premiums last week, the average premium at $32.20 on average, which means some are less than that, some would be more than that for a basic plan, that's $5 less than the actuaries had estimated, so a pretty significant savings for 2006. I think probably to the tune of $4 billion plus it will cost the government less, which is assuming that we have pretty full enrollment which is great news for taxpayers, beneficiaries the like. The premiums will be less. So those are the five tenets. Again, voluntary, catastrophic, limited income, employer coverage, and cost. So those are the five things to remember basically about the Medicare Modernization Act.

When I talk about the daunting task of enrolling beneficiaries, I also like to divide those up into five different groups, because each of those groups has a different focus. I already mentioned one group

and one focus, that's the employer group, and those who would have creditable coverage, or coverage that's good as Medicare. That group we expect about 10 million of the 42 million beneficiaries will be included in that group. The second group is those that are dual eligible. I mentioned them as well, Medicare and Medicaid already. There are 6.2 million or so of those individuals who will be converted from the Medicaid program into the Medicare program. If they do not choose a plan this fall, we will choose one for them so that none of them will be left out and fall through the cracks. And they will have an opportunity to change plans, frankly every month next year, if they're happy with what they have, they can change to a different plan without issue. So that's two groups so far. Employer groups, and duals. There is also a group of those who would qualify for the limited income subsidy, who have income levels higher than that or resources higher than that so that they could not qualify for Medicaid, but may still qualify for extra help. And as Dr. Kelman mentioned this morning, I'm sure we're working very closely with the Social Security Administration to identify those individuals, who if they can't afford to pay premiums, so on and so forth, they can still get the help that they need. So there are about 8.2 or so million of those individuals. I don't know how many will actually identify. Similar to the Medicaid dual eligible group, the limited income subsidy group we would, at the end of the enrollment period, which ends May 15th, next year, if we have found individuals who have signed up for the limited income subsidy who yet have not enrolled in a plan, we will enroll them in a plan. We will facilitate their enrollment after the end of the open enrollment period, so that they too can reap the benefits that they've applied for but for whatever reason didn't choose a plan. So again, dual eligibles, employer subsidy, limited income subsidy, the forth group if the Medicare advantage plans. These are the HMOs and PPOs that contract with the Medicare Program to provide a more comprehensive list of benefits. We'll have about 6 million beneficiaries in that by the end of the year, so those individuals will be rolled over into a plan that has a drug benefit come January 1st. So about 6 million Medicare Advantage, 8 million limited income, 6 million duals, right there, that's 20 minute, employer subsidies another 10 million, that's 30 million so that leaves us with about 12 million general Medicare population. Of those 12 million, probably another 2 million have something called Medigap coverage, or Medicare supplemental coverage that includes a drug benefit. Typically for that entire supplemental piece, including the drugs, the premiums can be anywhere between $300 and $400 a month. I know this because my father was paying it for a very long time. It was like, Dad! The drug benefit would be right for you.

Obviously from a subsidy perspective, the drug piece itself is significantly less expensive for beneficiaries than Medigap coverage. So hopefully we'll be reaching out to that group as well. I think it's important to look at those groups because it's slightly less daunting to consider how many beneficiaries already have had action taken and were really focusing on the 20 million that are limited income subsidy that aren't duals and just the general population to find out how we can give them more information.

And speaking of more information, there are three basic ways that we expect people to get detailed information. The first is our phone number, 1800Medicare. Before the MMA passed, we had 400 customer service representatives that answered questions 24 hours a day, 7 days a week. Remember the Leslie Nielson commercial where he's tripping over phone cords in our customer service center. I thought that was very funny. Well, we've gone from that sort of joking around getting the word out about 1800Medicare to adding, we've got a couple thousand—we added a couple thousand customer service representatives to deal with the response from the discount drug card that we put into place last year. We'll have 9,000 in place before November 15th in order to take the significant volume that we expect around the drug benefit. If you were counseling a patient, one thing I would suggest you tell them is to not call us on November 15th, because they will get a busy signal. I suspect everyone and their brother will be calling on November 15th and that's probably not the day to call. But otherwise, we're around 24/7 to answer whatever questions people have. Some people, and more importantly, partners in particular or family members are very sophisticated and love using the Internet, so we'll have all sorts of information available on the web. I suspect Jeff talked about that this morning at www.Medicare.gov. Always available. Choices of plans, so on and so forth, will be there including everything from formularies to premiums and copayments and the like. And finally I think most importantly for beneficiaries, is face to face counseling. That beneficiaries need to be able to bring in whatever paper they have or their scripts or whatever it happens to be and say help me. So we have been, we've increased the funding that we provide the states so that they can do more face to face counseling through a program called the SHIP program, the State Health Insurance Assistance Program. But they are really only the tip of the iceberg. We've been, as you may have read, going around the country with our mobile office tour, bus tour, talking to partners all around the country, particularly in big markets to get as much community involvement as at all possible. I gather there was a comment this morning about making sure that we include physicians in that. I suspect it just depends on the community. I

know that we have in the past, but I think it's a really critical element because I think the physicians and the pharmacists are probably the two most trusted advisors when it comes to this group, particularly around the drug benefit. So I'm quite sure I'll be spending more time with my friends at the AMA and the state societies, to help us figure out how to make sure that physicians are involved in that community effort.

So I know that's kind of quick but that's the basic five, five and three as I call it of the Medicare Modernization Act, and all the things that we're thinking about. It's obviously slightly more complex than that, but to give you a sense of where we are and what it is that we're up to, we really want to reach people where they live, work, play and pray, as broadly as we can get them. That's how we need to reach them and we really are focusing on all four of those fronts in order to get people at least aware of what's going on so they can make a decision about what's right for them. And the question of what's right for year really is going to depend on which of the five groups you fall and your ability to think about how much you want to make in terms of monthly payments, so on and so forth. But I think beneficiaries will be very surprised when we announce the plans and the premiums, probably mid to late September, how many affordable options are available to people all around the country, which is quite a relief to someone who is spending time making sure that we get all the plans and that competition and market forces help keep the prices down. And that is from an internal perspective, that's exactly what we've seen, so I'm very pleased with what we'll able to offer. I don't know where any of you are from but I think everyone will be pleased that there is an option that is far more affordable than anyone thought would be possible in 2003. So, there. That's pretty good, 1:30.

Mr. Kuhn: Not to impinge too much on our schedule, but if anybody has any quick questions for Leslie.

Dr. Castellanos: I would appreciate—does anybody have any questions specifically? For Leslie? Dr. Urata?

Dr. Urata: Anything about the marriage penalty? I asked the question this morning, I thought I'd ask you.

Ms. Norwalk: The way that the, I'm presuming you don't mean the tax code. [laughter] The way that the statute reads is basically it is both a plus and a minus. It's not necessarily a penalty. And the reason that is the case is that if you, it's actually looked at households. It's not—I can't remember if that's

statutory or regulatory. It's really the Social Security Arm piece. The Social Security Administration is implementing that, but the reason it can be a positive is if there is only one income or if there is a number of dependents in a family, you actually have a higher income level, so in a sense, it can cut both ways, depending on the particular household. If you've got 3 or 4 dependents, even if you're married, it may be that you can have the income of 5 people and still qualify. So I don't look at it as a penalty. I look at it as a more adequate approach to what's actually going on in the household in terms of their ability to pay for drugs, generally, the household at large. So it'll be interesting to see when we get the limited income subsidy information back, how much of it is helpful and how much isn't. So, I do think it's statutory. I don't remember off the top of my head.

Dr. Johnson: Administratively, when can we expect this year a fix on the Physician Fee Schedule? [laughter]

Ms. Norwalk: Well, there, we, when are you going to stop beating your wife? Yes. [laughter] We are doing a lot internally to figure out what it is that we can do legally around the SGR. I think any way you slice it, a fix is expensive. I know that we've been working closely with Chairman Thomas to figure out what might be possible from a legislative solution as well as an administrative solution. I think that we're also working closely with the actuaries, to figure out even if we did, from a legal perspective if we had the ability and this is all speculative, if we had the ability to take drugs out of the SGR retroactively, I mean, which by the way, may depend on the year in which, not the ability to do that is not the same every year. Because you've got different statutory language implementing payment reforms, like 2003 for example, 1.5, 1.5, so even if we were to do that, I think there is still in 2006, you would have a negative payment stream. So I think that there is still a fair amount to do even if we were to do something administratively, but I haven't seen as of yet the definitive legal analysis as to where we are and that I know it's something that we've been looking at. Because we've been watching everything closely and I think that the likelihood of timing for the Fee Schedule to come out is probably October 31st, or November 1st, we have a lot going on with Fee Schedule.

Dr. Johnson: This council has give you good counsel and plenty of good recommendations. [laughter]

Ms. Norwalk: I have seen it.

Dr. McAneny: Yes, one of my concerns has been, was really put out nicely in this Health Affairs article that came out of University of Maryland, Baltimore. Right in your backyard there, but they talked about the fact that they thought 38% of enrollees were going to end up in the doughnut hole. And since a lot of us are going to be seeing a lot of those patients who end up in the doughnut hole, how do I explain this to them, and how do we help those people who have that $5100 gap.

Ms. Norwalk: Well, here's how, there are number of different answers to that question. And I think one of things that we're hoping to announce the next couple weeks as we go through the drug plans to figure out what the analysis is, let me explain one thing. The standard benefit design that Congress passed, which said you have to do this or something actuarially equivalent to this has a $250 deductible, 75% coverage between $250 and $2250, then the infamous doughnut hole or coverage gap or coverage holiday or second deductible or pick your favorite term, I mean that is between $2250 and $5100 before the 95% catastrophic kicks in at $5100. That's just for the senior benefit design. It could be, if you add up all the out-of-pockets, including the first deductible and that 25% in the first coverage piece, it $3,600. That's why you might see 2 different numbers, just FYI. One of the things that we did in working with the plans is to say, a lot of plans didn't want a deductible, for example. And said no beneficiary wants to pay out-of-pocket in the beginning, so a number of plans have applied to provide a plan without a $250 deductible. Other plans, one of the things that we did last year earlier this year, was to allow plans to participate in a demonstration that would change how we pay them so that if they so chose they could not have a coverage gap, or not have the entire coverage gap. So one of the things I also anticipate us putting out at some point is specifically what would be available to beneficiaries, both at a standalone drug plan as well as a more comprehensive plan, an MA plan, or Medicare Advantage plan. So which I do think will be more widely available to people. So there will be options that beneficiaries will have that may provide better coverage than the senior benefit design. One of the things they may want to consider is praying a slightly higher premium in order to get coverage that fills in at least part of that gap. And I do think that will be available. It really depends on where you're practicing, though.

Dr. Castellanos: Leslie, Dr. McClellan made a comment. He said there's no doubt in his mind that any effective payment system in Medicare must recognize that the physician are the most essential part of

the solution, and that you're working closely with physicians to develop better ideas for physician payments. Any comments on that comment?

Ms. Norwalk: Well, I don't think it's—it's great to comment on your bosses comments. He's brilliant! [laughter] Absolutely brilliant. Who's going to report back to him. Leslie said you were brilliant. I don't think it's any secret, one of the things we've been spending a lot of time on is working on pay for performance issues, and what can we do to as I'm sure many of you know, Tom Scully, he used to Medicare is a big dumb payer. I think it is a great quote, and my all means, 100% accurate. It's exactly what it is. It is a system that was put together piecemeal over time through members of Congress, where one payment system has nothing to do with the next payment system that was developed, depending on whenever that statute was passed, so you've got home health agencies with episodes of care, you've got DRGs, you've got who knows what? But everything is very different from the next one, and the question is how is it that we take a system, not just that, but in addition to the physician system, and instead of paying for every service that's provided, regardless of the quality of care, so on and so forth, what can we do to make sure that the entire payment system that Medicare has as a whole is rational. How much can we do today? Given that a lot of basically all our payment systems are statutory? What can we do to make it more rational without statutory change, and how can we approach it in a way that we can get all provider types behind a rational approach to a payment system where you don't have 6 different ways to pay for rehab for instance, depending on where you get the rehab, whether it's a long term care facility or from home health wherever it is that you get that, can we make the system more intelligent? In order to do any of that, it's quite clear if we want to pay for performance, that physicians are going to be at the base of any decision that we make regardless, frankly of whether it's just the physician fee schedule fix, but I think even more broadly, because obviously physicians have everything to do with where, at least in many instances, of where patients end up in terms of what their next post acute care setting is, for example. And we ought to do both what's right by the patient as well as right by the government. We ought to do things based on that notion, how can the patient be better as opposed to how can I maximize the payment of a particular facility type, for example? I don't think it's any great news, but it is something that we've been looking at internally. And it is remarkably difficult to reconcile all of those things in a way that where we can make forward progress, but I think the importance of it doesn't make any difference how hard it is. It's something

I think we really need to do. But there is no doubt that physicians are the most critical component of all of that in order to make it work in the long run. So.

Dr. Castellanos: Thank you. Any other comments? Well we certainly appreciate your being here. Invigorate us and we appreciate the—

Ms. Norwalk: I'm not Tom Scully, but thanks. [laughter]

Dr. Castellanos: You're much better looking than Tom Scully. [laughter]

Ms. Norwalk: I'll tell him you said so, thank you! Thanks everybody. Have a good productive meeting. I'll look forward to hearing the specifics, the outcomes, and suggestions that you have. Oh, just in terms of one other small piece of follow up. Dr. Kelman mentioned that someone here said something about the manufacturer drug assistance programs, and whether or not it counted toward true out-of-pocket. I think that the short answer is yes it does. The longer answer is it may be a kick back, depending on how it's set up, so the Centers for Medicare Medicaid Services does not do kick back as the Office of the Inspector General. We've been working closely together to try and come up with something that makes sense. I think the short answer for that piece is that the devil's in the details, because you could set it up in a way that it wouldn't be a kickback and it's just a matter of how they're put together. We obviously want beneficiaries to have access to these programs that can help them in the doughnut hole for example, but we want to do it in a way that isn't basically a drug company saying here, take my drug. We want to do what's right for the beneficiary and both the appropriate drug as well as the out-of-pocket.

Dr. Grimm: [off mike] One that concerns Leslie, thank you very much for that presentation. I think of the primary concerns about the sustainable growth rate is the burden of the expense of this being placed completely on the backs of physicians. Whereas a disproportionate amount of the money that's expended and a profit from medical expenditures are made by everyone else. And while this is not a regulatory issue, it's a statutory issue, I understand that, but as an organization, our organization here, we are extremely concerned about that for our constituents. That the burden of American medical care and cost is being placed on the physicians and not equally shared proportionately by the amount of money that's there being reimbursed. And I'd like your comments about that idea.

Ms. Norwalk: I think it goes hand in hand. I suspect a lot of that is the case simply because of where the economy was over the past number of years. And because the sustainable growth rate, by its very

nature, takes into account gross domestic product, and so on and so forth, where the other payment schedules do not, I haven't looked at this but I would be willing to bet some years, the physicians did better than other provider types. But at the end of the day, your point is well taken. But it is statutorily driven, and that same type of [solemn?] mentality that I was mentioning that leads Medicare to be one dumb payer, i.e., they aren't linked to each other. They really have no relationship. And in fact, was ever, whatever the brilliant idea was of the Congressional member of staff, or was working at that point in time, whenever it passed. Oh, here's a payment system we could try, and oh, this works for inpatients, and this one for home health, and so on and so forth. And they really don't intersect. Some are your calendar year, some are fiscal year, some are earlier, some are later, I mean it's—because everything is, because the payments are statutorily driven, they don't have an order to it that if you were designing it from scratch that would make sense. I think that maybe it's something that Congress would want to consider if they're looking at SGR, if or when they look at SGR, whichever's the appropriate term, whatever point in time it is, is there something they can do to make it more rationalized? The one thing I would say to your point more specifically is any time you bring in another payment system, it becomes far more complicated. So if you're linking your own payments to a different provider type, you'll make it—that legislation will be a lot harder to pass, just sort in my, Leslie Norwalk's view, not CMS's view.

Dr. Sprang: We were discussing is really want to have more incentives for physicians to try to cut the overall cost, if what we do cuts costs for hospitals, hospitals pay less, and there's no benefit whatsoever for physicians. If there's some incentive plan, and they're interconnected, it make a lot better sense for physicians and maybe physicians could actually be convinced to be more cost effective in the other areas.

Ms. Norwalk: That's another thing that I know that OIG was going to take another look at that's game sharing. I think the Hill actually has some game sharing proposals out there which are very similar to that. I think the OIG has permitted game sharing, which is allowing physicians to take, have the benefit of hospital savings. They have really only done it when it comes to supplies and things that are specifically medical savings, i.e., mainly because I think concerns about under treatment if you will, and oh, as opposed to over utilization it's under utilization, but I think from a supplies perspective, they have said it's OK. I thought that there had been some discussion on the Hill looking at game sharing more broadly which would allow physicians to share in hospital savings for example, without it being either [stork?] or kickback

violation. Some of the other things that we're doing as Herb just mentioned to me is the physician practice group demo, and in fact I was just in I think I was in Montana. I was in Billings a couple weeks ago, and met with a hospital that's participating in the demonstration. And they said yeah it's great, we're saving all this money because we're doing fewer surgeries. Of course the hospital's getting less, but the physicians, the group itself feels it's a real important part of making sure beneficiaries get what it is that they need and no more and can save the program as a whole. So I think as the Medicare Program, generally, we have some pretty significant authority to do demonstrations. And statutory authority allows us to change how we pay people in order to demonstrate something in particular, better efficiency for example, or whatever it happens to be. And so this is one of things, actually there are quite a number that are statutorily mandated, but the concept is well if this works, is there a way that we could role it out more broadly, if we had more statutory authority. So I think your point is very well taken, and we have been looking at it in slices, and I suspect if the results are positive, it might be something that we might request to Congress to take a closer look at.

Dr. Castellanos: Again, thank you very much. We appreciate it.

[applause]

Physician Fee Schedule and Outpatient Services Proposed Rules

Dr. Castellanos: I think we need to continue on the program. We're running a little late. But we can probably make a good bit of that time. Our next, it's really not a change of pace, but our next two topics to include both the Physician Fee Schedule and outpatient services proposed rules, will be combined and presented in a panel format led by Mr. Steve Philips. And Mr. Jim Hart. Since January of 2004, Steve Philips has been the Director of the Division of Practitioner Services in CMS. Mr. Phillips is responsible for the oversight of all policies associated with Medicare payments to the health care practitioner, including physicians. His responsibilities include oversight of the Physician Fee Schedule, including publishing the annual updates in the *Federal Register*. Mr. Jim Hart is the Director of Outpatient Services at CMM. He is responsible for the oversight of payment policy for the hospital outpatient departments and ambulatory surgical centers. Mr. Phillips and Mr. Hart are joined by Dr. Edith Hambrick and Dr. Carol Bazell, both medical officers in the Hospital and Ambulatory Policy Group. Mr. Phillips, would you like to begin?

Mr. Phillips: Thank you. Good afternoon, thank you Council for the opportunity to be here today to review our proposed Physician Fee Schedule update for 2006 and especially although, unfortunately she's left the room, but I wanted to thank Leslie Norwalk for answering all of your SGR questions. [laughter] Just a kind of a fine print footnote, as is always the case when we appear before you, final publication of the Proposed Rule, we would urge you to submit formal written comments on particular issues that you wish for us to consider as we prepare the Final Rule, and in that regard, the comment period on the Proposed Rule closes September 30th. Of course we always welcome your input at these meetings but that's just in terms of the formal rule making process, the way to get comments on the record.

This slide goes through some of the most significant changes. We included in the this years proposed fee schedule. And among these, I think one of the most significant is the change for methodology for calculating practice expense RVUs. I'll discuss the proposal in a little more detail later, but the general point here, is that we're proposing to switch from what we term a top down methodology currently to a bottom up methodology and basically what that means is that currently, we use data from the AMA socio-economic monitoring system survey that was actually discontinued in 1999 as the basis currently for determining practice expenses. And then those costs are provided through the SMS survey at a specialty level, the allocated down to the individual procedure codes and rather than continuing to use that top down allocation for purposes of the direct practice expenses, we're proposing to rely on a bottom up, which essentially takes input values that have been reviewed by the Relative Value Update Committee, or the RUC, the RUC's work group to review that it was established and is ongoing to review practice expenses for individual codes. As I said, we'll get into that a little bit more in a minute. In addition, we've included the proposal to adjust payments for certain imaging procedures that are performed on contiguous body parts. Similar proposal is included in this year's Outpatient Prospective Payment System Proposed Rule, which as Jim Hart will describe following my presentation. This change was also recommended by MedPAC in its March 2005 Report to Congress. And we've also proposed several changes to the calculation of the malpractice RVUs.

OK, as far as the specific changes that we are proposing the practice expense calculation, first of all, we just say that we believe that our current methodology which places a great reliance on the AMA's SMS data and the supplemental surveys that have been submitted by specialty societies over the years, to

supplement the SMS data because it was discontinued in 1999, that the reliance on that methodology was appropriate given concern about the original alternative data source that we have available, the Clinical Practice Expert Panels, or CPEP, which, as many of you are probably familiar, were developed also in the mid-90s through panels established by the agency to review and develop the inputs for individual codes and so in looking at the 2 available sources at the time, we selected the AMA's SMS data and the top down methodology to allocate that specialty specific data down to the individual codes. But over the years since that time, as the RUC practice expense workgroup has reviewed the CPEP data, that we now believe that most parties involved actually would tend to agree that the data that has been reviewed for the codes by the RUC, generally captures the relative practice expense costs of performing each service. On the other hand, although we now have at least proposed to accept supplementary SMS survey data from 10 specialties, that have gone through the process, since 1999, to collect and submit data to supplement their SMS data, most specialties have not submitted such supplementary data. And we think that this calls into question whether the CPEP RUC practice expenses should continue to be scaled to equate with the SMS data, which was essentially the top down methodology.

I would note, as I said, that while we're proposing to use the CPEP RUC data for allocating direct practice expense, we are not proposing to use it at this time for the indirect practice expense, specifically the CPEP RUC data do not include indirect expenses attributable to individual procedures. Indirect expenses are currently available only through the SMS data and so therefore, we propose that the current indirect practice expenses would continue to be used, although we're soliciting comments on the most appropriate ways to determine indirect expenses going forward.

Also another aspect of our proposal on calculating practice expenses relates to the non-physician work pool, specifically, to eliminate that pool. At this time, the major specialties that comprise the pool, radiology, radiation oncology, and cardiology, have all submitted supplementary survey data. And in addition, the RUC has reviewed nearly all of the codes in the pool. And therefore, we believe it's also reasonable to conclude that the CPEP RUC data more accurately reflects the practice expenses of the codes in the pool rather than the amounts that are calculated through the special calculation that currently applies to the codes in the pool.

Now we recognize that for some codes, the bottom up methodology does result in significant shifts in the RVU amounts. And would note that we've also proposed to phase in the methodology using a four-year transition period, blended with the current RVUs. This would allow codes to be referred to the RUC for further review if the affected specialty believes that the code is misvalued, prior to full implementation at the end of 4 years.

As I said, the second major area where we have proposed a change is related to the multiple imaging procedures and discounting the second and subsequent procedures. Medicare has a long standing policy of reducing payment for multiple surgical procedures performed on the same day by the same physician on the same patient. And in those cases, full payment is made for the highest price procedure and each subsequent procedure is paid at 50%. Currently multiple diagnostic imaging procedures, however, are paid at the full payment for each procedure. We propose to extend the multiple procedure reduction to diagnostic imaging procedures identified, or grouped into 11 code families. This reduction would only extend to the technical component payment of the case, and in the event of a billing of the global rate would only apply to the technical component of the global rate, full payment would continue to be made under the proposal for the professional component.

As far as malpractice RVUs and changes to the calculation. We're concerned that the malpractice RVUs are not inflated or deflated due to aberrant data that we discussed to some degree in our response to comments at last year's Final Rule and indicated that we would continue to look at this issue and specifically, we're proposing to remove the malpractice data for specialties that occur less than 5% of the time in our data for procedure code. Also, we note in the rule that the RUC Practice Liability Insurance Workgroup wrote to us recommending several changes to the crosswalks used to assign risk factors to certain non-physician specialties for specialties for which we did not have any other data available. We're proposing those specialties that were identified as potentially being assigned to a risk fact that was too high to use the lowest risk factor of 1.0 for specialties rather than the all physician average, which is actually higher than some physician specialty groups. Some of the affected specialties that are changed to the 1.0 risk factor would be licensed clinical social work, clinical psychology, chiropractors and physical therapists.

Just a few other issues. We mentioned, we had to at least include the 4.3% update, and of course what the Reg, essentially, as Leslie Norwalk describes, solicits comments on going forward with ideas as far as addressing the SGR calculation, as well as explaining the administration's efforts in working with Congress and the medical community on the issue. We also include a proposal to expand our list of approved telehealth services. Every year we have a process whereby we accept requests to add codes to the list of codes that are approved to be provided using telehealth, and this year, we're proposing to add medical nutrition therapy to the list. We include a specific proposal to change geographic practice cost index payment localities in California. This is an issue, particularly last year, we received a number of comments relative to Santa Cruz and Sonoma Counties, being included currently in the rest of California payment locality and actually we received a proposal from California Medical Association for a demonstration to address that issue. Ultimately, we were not able to go forward with the demonstration proposal, but we did include this proposal as kind of identifying what we believe are the worst case scenarios and recognizing the efforts of the medical society to go through our process that we've established for payment localities.

We include a notice of the expiration of the moratorium of the imposition of the CAPs on therapy services. This is essentially just that; a notice of the expiration of the statutory moratorium on the per beneficiary cap for payments for therapy received within a given year, specifically that effective January 1, of 2006, that moratorium will go away and the therapy caps will be reinstituted barring any further action by Congress. We also finally, we solicit comments on changing the payments for teaching anesthesiologists. This is an issue that also has come up in prior comments on the regulation, and has to do with the interaction particularly among teaching surgeons and anesthesiologists involved in the same cases, where our policy provides for surgeons to be able to bill at 100% for both cases. If they are provide in the critical portion of both of those cases, whereas anesthesiologists are enabled, under the statute, to bill under the medical direction policy at 50% for both services, and would like to be able to bill on the same basis as teaching surgeons. So we address some of the issues involved in that and solicit comments on that idea.

One other thing, well 2 other things actually that are not on this list that I just wanted to highlight: One is a proposal to expand the coverage for glaucoma screening to the population of Hispanics age 65 and older, based on evidence, research evidence that group to be at substantially higher risk and also a proposal

to include, as diagnostic radiology tests, subject to the Stark restrictions, as well as radiation therapy, nuclear medicine to the extent that it is used as diagnostic radiology or therapy, radiation therapy is proposed to be added to the list of services subject to the Stark self-referral regulations.

The next slide just indicates that we would particularly appreciate Council's views about any operational impacts of these proposals and then where you can find the Propose Rule on the internet. Thank you very much.

Dr. Castellanos: Well thank you, Mr. Phillips. I'm sure we're going to have some responses.

Dr. Urata: Could you clarify the proposal to extend the multiple procedure reduction to technical component only services, where you're paying half or something? What does that exactly mean? So if a trauma patient comes in and gets a CT scan of the head, and then chest, and then X-rays of the femur that's fractured and things like that, you're going to pay less because it's all done in one day?

Mr. Phillips: Well, the proposal actually identified families of codes based on contiguous body areas as well as the mode of imaging. So I believe in the example you described, I don't think—

Dr. Hambrick: An example that you gave, because it's a CT of the head, which is not contiguous to the chest, that would fall out there, and because the extremities are not part of, if you did two studies, say two CTs of the upper and lower arm for some reason, whatever, then that would work in that instance. So no in your example that you gave, no there would be subject to…

Dr. Urata: How about chest and abdomen, are those considered?

Dr. Hambrick: Yes, yes. In the proposal they are.

Mr. Kuhn: The objective here is that you only read the patient once, not twice. There are certain things that are built into the payment that are duplicative, that we are trying to see if we can find ways that we can get better efficiency. So that's what the proposal's trying to get at. Examples like that.

Dr. Przyblski: I have a long list. Again, as usual, but just to follow up on that comment, why did you choose only the technical and not the professional side of things, because similarly, the explanation that a radiologist may have in doing things, reviewing the history of the patient, etc., is also duplicative, and if they're reading a series of images, just like the surgeons are subjected to those restrictions, why is the professional component not part of this package?

Mr. Phillips: That's a good question and certainly as I mentioned this is a proposal, and that would constitute a valid comment. I think we proposed the, to focus the reduction on the technical portion for a couple reasons. One, as I said, started out as a recommendation for MedPAC was to only focus on the technical portion when we starting from that recommendation, and did analysis of values or the inputs in those services that are constitute the direct practice expense inputs, we were able to identify specific things, such as Herb mentioned, greeting the patient, lining the patient on the table. As far as the professional component, and actually interpreting the images, there are different ways I guess that you can argue that. There's different ways I guess you can argue that. One is that it's the same work involved if you take multiple images, you still have to interpret each image, but that would certainly be something we'd be open to comment on.

Dr. Przyblski: May I continue? On that malpractice side of things, as you may or may not remember, I chair the workgroup the RUC on PLI issues and I'm pleased to see that some of the areas that we've been going into that you're looking at favorably and that's very much appreciated. The 5% removal, I think, goes part of the way to where we were going with the dominant specialty approach and first question is, is that simply off the table? Using a dominant specialty approach? And the rationale for that has been that all of these methods weight average everything and so it penalizes the higher cost provider and advantages the lower cost provider in terms of professional liability cost. This helps some, but it doesn't go all the way to account for neurosurgery, among the highest professional liability cost providers. Can you still consider dominant specialty approach?

Mr. Phillips: Again, you know, that's something that would fall within an area that could be commented on. It certainly was mentioned in the discussion on the malpractice and the Proposed Rule. Our view of the dominant specialty as we have discussed in response to comments and verbally as well with the work group is that consistent with the other calculations in the fee schedule system, as you mentioned we use a weighted average of all the data that in this case, all the specialties that actually provide the service to capture the real price, if you will, of providing the service to Medicare as the payer. But we would distinguish, I guess, the change that we made in terms of the 5% threshold as trying to get aberrant data, that we recognize some in some cases, whether it's the, if the physician has reported the specialty code wrong or whatever, reported the procedure code wrong, that that should not impact on the calculation of the

malpractice RVUs. So it's really distinguishing between a few physicians in a specialty that are actually doing a procedure, questionable whether they're, I guess the distinction between the dominant specialty and the proposal that we made would be whether we think the physicians are actually doing it whether it's only a small portion of them are not, or it's aberrant data.

Dr. Przyblski: In terms of weight averaging, looking at the data, the liability insurance premium data that's being used, one of the frustrations has been that this is old data that's being used. It's weight averaged over three years, and therefore is not capturing what's happening currently. And there have been discussions about alternative sources of data and I think there have been some recent emails about the status of that, at least from AMA staff to CMS and I was curious to know where we are in the PIAA as an alternative source of data.

Mr. Phillips: We are continuing to look at that. I think that now that we've got the Proposed Rule out the door, I think we can focus on that a little bit more. One of the issues with that, at least the last time we had a discussion, as you'll recall, was in terms of going forward, what role would CMS play in the collection of the data. And that is something that internally, there is a process for looking at that, as well as if any commitment of financing would be involved, that all of that would have to go through that process. It's something that we're looking at, going forward to the extent that that was the path that we went down to collect the data would have to go through that process.

Dr. Przyblski: Would you indulge one more?

Dr. Castellanos: Please.

Dr. Przyblski: Thank you. On the practice expense side, I'm curious to understand what is being transitioned over those four years? Is it the supplementary data that has been submitted by a subset of specialties, regarding indirect expenses, or it is all the work that the PEAC's done up until now and if it's that also, what has that data been used for up until now? Or hasn't it been? I guess I got somewhat confused.

Mr. Phillips: The indirect is not being transitioned. The indirect is being carried forward based on the current indirect values for the codes, with the exception of the supplementary survey that was submitted by the specialties this year. That data's being entered in as the indirect values for those codes. And there's no transition. The transition is happening on the direct input side. And as far as the work that the PEAC has

been doing, the way the top down methodology works, is that it started with those SMS cost pools and then allocated it to the SMS specialty cost pools, and then allocated it to the individual codes, based on the CPEP data within those codes. And so you could have different PE per hours going into the same code from two different specialties. The CPEP PEAC refined data was really only being used to allocate the SMS data basically. Now it is being used to calculate the direct practice expense input. The SMS data is not being used for that, or won't be used for that once the transition is complete, under the Proposal.

Dr. Grimm: Yes, you mentioned a comment about the radiation therapy and nuclear medicine and the relationship between those two and I'd like you to sort of explain what you mean in terms of that relationship and what's being questioned here, because nuclear medicine, obviously, PET scanners know [these?] are being used for the diagnostic and targeting issues for radiation therapy, and like you to explain what the issues, what Stark issue is here.

Mr. Phillips: OK, well I can give you a general explanation. I'm actually not the best person to give you a lot of detail, and I can put you in touch with that person, but the general proposal is that we've looked at nuclear medicine previously, in terms of adding to the list of services subject to the Stark Rules and at that time decided that it was not, should not be included. I think that was in the late '90s, and again, this was part of MedPAC's recommendation in March. We reexamined it, and I think based largely on the expansion of the provision of the services directly in physician's offices rather than hospital-based, felt that it was appropriate to make the proposal to include it as part of the services that are statutorily under the restrictions.

Dr. Grimm: Can CMS make that determination? Does the Stark Law allow CMS to define who and what services are going to—

Mr. Phillips: Yes. The law identifies the broad scope of services that are subject to the requirements, and then CMS determines within that broad scope what particular services are included.

Dr. Hamilton: Just wanted to ask you about the nuclear medicine prohibition under the Stark regulations. I can understand that what you said relates meaning to PET scanners. But there are many endocrinologists, such as myself, that use very limited nuclear medicine facilities in their office and have for many, many years in terms of the thyroid gland, radioactive iodine. Would that be included in this same

thing, because that would really impact a great deal of patient care in a small way at each situation, but it would be quite important to many people who do this kind of work.

Mr. Phillips: I don't know if I could say specifically myself. It's something we would have to asses, whether, with the folks who actually are the experts. I only mention it as part of our Proposed Rule, but it was actually originated by another office to include some…

Dr. Hamilton: What office would be particularly involved, that we might inquire of?

Mr. Phillips: Well, the Division Director is Don Romano.

Dr. McAneny: Won't that still fit in the In Office Ancillary Exemption, if you use it as part of your practice, and the question really for the PET as I understand that part of the rule was more people having economic interest in a PET scan to which they referred patients, but it wasn't done as part of their practice, under the same roof, type idea. Is that not correct?

Mr. Phillips: Again, I would have to, I only mention that in terms of the Rule. In terms of the specifics of the operational specifics, we'd have to refer to…

Dr. McAneny: I had a couple questions as well. First was that there have been a lot of new procedures that are now covered by Medicare in terms of the Welcome to Medicare physical, the colonoscopies, the screening processes, all of these kind of fees were generated, and increased the volume and intensity of physician services considerably. Is there any break out in the work that you have done in your office, to look at what percent or how much of those services were done? And was there new money that was put into the target, to account for those new services?

Mr. Phillips: Yes, our Office of the Actuary actually does the calculations of the SGR and they, for the statutory benefit expansions do make an estimate of the services directly, as well as estimate. But the downstream effects will be on follow-up services.

Dr. McAneny: Can you share any of those numbers with us?

Mr. Phillips: I don't have them with me. We could follow up with a—

Dr. McAneny: Was there new money put into place to account for those particular services, though?

Mr. Phillips: Yes, what the, to the extent that it would result in an expansion in level of expenditures, there's an adjustment upward of the SGR target.

Dr. Leggett: Thank you. I just have sort of a very basic, real world question. I'm curious as to what level of thought was given to the potential affect, or combined affect of the decreasing reimbursement fee schedule, let's just use cardiology for example, and combined with the current reimbursement structure for multiple procedures. Let me give you an example. Let's take an 80-year-old patient who was referred in from 70 miles away for catheterization. And the very first question out of that patient's family's mouth is Doctor, are you going to fix what you find today? Now, if this is a non-acute elective situation, let's say, the catheterization is done and an 80% blockage is found. Now, when you start looking at the situation from which some doctors are currently looking at it, which is the reimbursements they're going to have. They're getting paid full rate for initial procedure and half for the next. Frankly, what keeps that physician from sending that patient 70 miles back home, rescheduling their case a week from now, in order to recoup full payment for the next procedure? And while that may seem a little sort of unfair, it's already happening. And frankly, I think that's a disservice to the patient. I think it's a disservice to the family. Certainly as the population continues to age. But I'm not going to say some doctors are being forced into that pattern, because that's not true, but what's actually happening is some doctors are doing that. And so my question really is have you guys considered the impact that it's going to have on the people who have disease as it relates to the continued sort of chipping away of fee schedules, reimbursements, etc? Because our risks in performing any of these procedures don't decrease because of reimbursement. Our risk is the same or even greater, certainly as the population ages.

Mr. Phillips: Well, yes, I would answer that by just saying that our objective in managing the fee schedule payment system is to pay fairly for the services that are provided. And so to the extent that we accomplish that, then the incentive will be only to do what's best for the patient and a fair payment will be provided. Now, in looking at the multiple imaging procedure reduction, for example, we as I described earlier, only looked at the technical component portion because that was where we felt there were pretty clear services that could be pointed to that would not be duplicated in a second or subsequent procedure and therefore felt that a reduction would be justified. But we are continually assessing our policies in terms of the incentives that they may have and certainly would not make payment reductions, just for reductions sake. It's really trying to balance the payments with what evidence indicates the resources are to provide the service.

Dr. Leggett: That's not really what I meant—I don't doubt that that's what you're doing. What I'm saying is the impact of what you're doing is actually changing behavior. And that change in behavior is impacting families. And so the end result is that whatever change you make impacts the patient that comes to the hospital. So it's not necessarily kind of, this elusive format of how you got where you are, I'm just really addressing what the demand is, what's happening, and the questions that are initially presented. And the ultimate question is doctor, why are you sending her home with an 80% blockage. I mean that's happening everyday.

Dr. Sprang: Just general again, as far as negative 4.3% which obviously we believe will have a negative impact on access to care. I'm an OB/GYN. I know Medicare doesn't do a lot of OB, but we take care of a lot of GYN patients and most OB/GYNs do both, so their premiums or costs are related to both. I think I know probably a dozen of the GYNs and I practice in Cook County, Illinois, which is a very high risk area, a dozen have left altogether, and that's because they can't survive. They can't keep their offices open. If we continue to increase our costs, which will happen, if we decrease our reimbursement, which is what's scheduled for now, those physicians that are still keeping their offices open will have to figure out how they're going to still be able to generate enough income. They're not going to be able to see more and more patients because there's only so many hours in the day. And they'd certainly be forced, if they don't stop seeing Medicare patients they're seeing, certainly stop taking new ones, so they can hopefully get newer patients that can reimburse them better, not so that they can make more money, just so they can keep their offices open. I think it's a serious problem, and in my area, it's absolutely going to happen. And there are other OB/GYN groups in Chicago now that don't take Medicare patients. And there will be more or there will be more who just take fewer. A lot of it is related to liability issues, so I'll go back to what was said before as far as malpractice data. We certainly believe that not current appropriate data is being used, and certainly the PIA has much more accurate data, much more current, and if you look back at some of the old data and then average it for three years, you're missing huge amounts of change. In Illinois, again in Cook County, 2 years ago, we had 35% increase. So if you're going to look back for the last 3 years you're not going to appreciate that increase for a long period of time. And right now an OB/GYN in Cook County pays $160,000 a year. You got to see a lot of people and do a lot of things to continue to be able to do that. So I think doing everything you can to make sure that the malpractice data is accurate is one important part,

and the other is you can't cut the reimbursement more because we're just not going to be able to keep our offices. It's not making more money. It's just being able to survive. And I so just ask you to consider that.

Dr. Powers: Thank you, I think, the [inaudible] methodology, something we've been looking at for a while. It sounds as it—we really haven't had chance to analyze it fully ourselves, because we were surprised frankly that this would happen, but it sounds like that would be a more fair way to approach the situation I the long run. The question is on the telehealth and I apologize because I haven't actually read the rule, so you're commenting only on nutritional service, it only addresses nutritional services, or is it telehealth in general? There's some comments for instance, the growing use of telehealth with stroke care.

Mr. Phillips: Yes, I mentioned that we were proposing to approve medical nutrition therapy, for individual patients to the list of approved services. We also received requests for group services, and we propose not to approve those on the basis that we don't currently have other services that are approved for providing in a group setting, and therefore, it reaches a higher level of evidence that has to be provided to support the request. You mentioned also the request for using telehealth for consult for a stroke patient, particularly with the administration of TPA. We received a request for allowing that where there is only one-way video. Currently our regulations require two-way video and audio, and so we've actually proposed not to approve that request, but solicited comments on the implications of using only one-way video, not only for this particular case, but what implications it would have in terms of other services if we would consider for telehealth, so we're looking for input on that issue from the community.

Dr. McAneny: In previous discussions we have looked at how CMS is monitoring the access of patients to physicians. And we were told that basically it was how many people called 1800Medicare or a survey that was done to see how many patients were able to get an appointment in X period of time, and it was at 72% of patients were able to, and therefore, it was considered to be not a problem. To us that meant that 28% of patients were not, and that did indicate a problem. And so at the last one we made a request which was unfortunately interpreted as belonging to the CAP program, but was truly intended to apply to the entire Medicare Program. Which is that is there a more accurate way to get an early warning system if there is going to be a serious access to the Medicare Program? As we look at this decrease that's schedule for the next several years, there have to be certain populations who will be more vulnerable, perhaps the dual eligibles, or certain specialties that may be in short supply that may be impacted before general

Medicare does. So our question was is the system, is CMS, looking at any specific indicators that might give us an early warning system that physicians are decreasing access for Medicare patients?

Mr. Phillips: No, I think that's a very good question. We have been focusing primarily on oncology patients to date, and are still working on that in terms of trying to match up prior periods with 2005, which is complicated by a lot of coding changes that happened. But I think that that will give us good experience that we can then take to identify specific measures that we can monitor as the claims come in. I mean we are able to start getting some very preliminary data within the first three or four months of the year. I emphasize that that's very preliminary, but I think that while, I am not aware at this time of specific measures that have been developed to look at, but that's certainly something that we can focus on to the extent that there would be a payment reduction next year, broader than just oncology to see what sort of impact it may have.

Dr. McAneny: If I may follow up on that?

Dr. Castellanos: Please, Dr. McAneny?

Dr. Simon: And I would say that currently the Office of Policy, in the Office of the Administrator as well as the Office of ORDI are working collaboratively in working with the regions in order to monitor and assess for any problems related to access of care or problems related to physicians taking care of those Medicaid beneficiaries as well.

Dr. McAneny: The question though, of using just oncology as the indicator may not be accurate because of the demonstration project, which was very helpful in managing to continue to see oncology patients through this year so that may have been artificially elevated, because of the demonstration project, so that may not be a good indicator of what's happening in the rest of Medicare. But it does raise the question, are you going to continue the demonstration project in some form? It was sort of conspicuously absent in this Proposed Rulemaking.

Dr. Castellanos: Dr. O'Shea?

Dr. McAneny: He's not going to let me answer?

Dr. Castellanos: No, he's not going to answer.

Dr. McAneny: He was trying, he was getting ready. You stopped him. [laughter]

Dr. Castellanos: Steve, I'm sorry, it looked like you were going to do that stone face approach. [laughter]

Dr. McAneny: I want to hear him answer.

Mr. Phillips: Well, we did, your right there wasn't a discussion in the Proposed Rule as far as whether we were going to include it, as you know, it's not, this year's demonstration was implemented under specific statutory authority, so it doesn't, didn't go through rulemaking, doesn't require that. At this point, we are evaluating the current demonstration and continuing to talk with affected stakeholders and have not reached any decisions as far as what the future may hold.

Dr. Castellanos: Good! Thank you. [laughter]

Dr. O'Shea: Steve, thank you. On your other issues, there was changes to geographic practice costs of index payment localities in California. Briefly if you could, where did this come from? Not just California, but where did it come from and why, and is it just those localities, or is this an example of just in California, but happening in other places in the country, too?

Mr. Phillips: Where it came from is that it has been an ongoing issue where the California Medical Association has identified specific counties that it believed were adversely affected by the current payment localities, and has worked through its process to develop a recommendation to CMS to resolve the problem that it identified. Ultimately what it came up with and proposed was a demonstration project that we were not able to go forward with, but given the specific situations in these counties in terms of the difference between their costs and the average costs of the payment locality they're in as well as the higher payment adjustments, geographic payment adjustments of the counties that they share borders with, we felt that the proposal that we put forward went at least, would address the worst situation, actually, the California proposal would have included 8 other counties and reconfiguring the payment localities, so this was actually just addressing the most obvious situations.

Dr. O'Shea: I think you're going to find that a lot. In other places, too. It may come up again.

Mr. Phillips: In other areas?

Dr. O'Shea: Yes. I'm just saying that, I'm just wondering why it was just California, because I've heard this before in other places you know, sometimes our payments are adjusted per geographic region so maybe we're going to have to update that.

Mr. Phillips: I guess I would emphasize the point about the problems identified by the California Medical Association and that they, we felt, made a good faith effort to go through our process of their developing a solution.

Dr. O'Shea: And you had mentioned Santa Cruz and Sonoma, those were the two?

Mr. Phillips: Yes.

Dr. Przyblski: Going back to the PE thing, I'd like the Council to make a recommendation and the background for this recommendation is that we've already gone through a PE transition between '98 and 2002 that had a substantial impact on a lot of physician specialties. 45% of many of our codes are reimbursed based on the practice expense. So if you take 100% of an RVU for payment of a service, almost half of that is on the practice expense side. You've proposed to completely change the system of how you're using practice expense to come up with those RVUs and essentially giving us a fairly short time period to figure out how it's being done, is it reasonable or not, and what the impact is on all of medicine is as well as specific specialties. So I would ask that the Council recommend that CMS delays implementation of the change in methodology of PE until the AMA and the medical specialty societies have an opportunity to review it in more detail and assess its impact.

Dr. Castellanos: Is there any discussion on that? All in favor?

[Ayes]

Dr. Castellanos: Opposed? Are there any other comments?

Dr. McAneny: I'd like to make a recommendation that or a request that CMS show us the number of the new increases of money in the SGR target that are attributable to the new benefits enacted in the MMA so that we can assess that affect on reaching the SRG target.

Dr. Castellanos: Is there any discussion on that motion? All in favor?

[Ayes]

Dr. Castellanos: Second? Good. Opposed? Are there any other discussion?

Dr. Grimm: Just one other recommendation, this morning if I may [inaudible]. PPAC recommends that CMS allow electronic resubmission of electronic claims.

Dr. Castellanos: Denied.

Dr. Grimm: Denied electronic claims. Thank you.

Dr. Castellanos: Steve for you, that was one of the discussion we had this morning with the PRIT and when there's a denied claim, as you all know, we have to resubmit that in the paper claim, that's the basis of that. Could you read that again, please?

Ms. Trevas: The Panel recommends that CMS allow electronic resubmission of denied electronic claims.

Dr. Castellanos: Is there any further discussion on that? All in favor?

[Ayes]

Dr. Castellanos: Opposed? Are there any other discussions or recommendations to be made?

Dr. McAneny: I'd like to redo our recommendation with references to what Ken had said earlier and change it a little bit. It's from C-2 from the previous one. We had requested last time that CMS develop a plan, so I guess what I would request this time is that CMS show us their plans to monitor critical subsets as possible indicators of barriers to access to care, and then the same language as before, but with the clear understanding that this applies to all of Medicare, and not just to physician administered drugs. Do you want me to—you don't want me to read that whole thing again, it's right there. Yes.

Dr. Castellanos: Dana, I'd like you to read it. [laughter]

Ms. Trevas: PPAC recommends that CMS present to PPAC its plans to monitor critical subsets as possible indicators of barriers to access to care, such as new versus established Medicare patients, patients without Medigap coverage, and specialty versus primary care patients and that CMS develop a plan to address possible declines in access before problems become widespread.

Dr. Castellanos: Is there any further discussion? All in favor?

[Ayes]

Dr. Castellanos: Opposed? Is there any other discussion or motions that would like to be made? Steve, I'd like to make one comment before you leave, and it's really a continuation of what Dr. Leggett mentioned to you. I hope that you recognize what CMS does impacts directly on what the physician does. But more importantly, it impacts on the Medicare recipient and what that physician does or doesn't do to that family, and I think that's what Dr. Leggett was trying to say. I have a letter from a urologist. He's been in practice for 25 years. He's had to borrow funds on multiple occasions to take care of his office overhead. He thinks this is totally unacceptable. He prides himself that over the past 25 years, he's been caring for the

greatest generation there ever was, the World War II veteran, but he now finds it impossible to continue this. The reimbursements are shameful. He cognizes that there are certain things he could have done from a financial viewpoint to supplement his income, but from a moral standpoint, he chose not to do that and he chose to support his community and the community hospital where he practices, and he recognizes this has been a financial disaster. You're putting the physicians in a box. There is a person who tried to do the very best he could in his community, and he's stuck, not being able to take care of the patients he wants to take care of. You're forcing us the physicians here to go into ancillary procedures to supplement, or make up the income that we're loosing on Medicare so we can take care of some of these Medicare patients. As we've said all along with AWP, and ASP, we have been eating that 20% on these patients that can't afford these drugs. We can't do it anymore. And I just hope that you recognize, and I apologize about the stone face. But we're dealing in real life situations and we're not dealing in financial or actuary issues, we're dealing with a real person, in real life. And I hope CMS recognizes what you do, the impact that you put on the physicians, and unfortunately put on the Medicare recipient.

Dr. McAneny: I have to make one more, I'm sorry.

Dr. Castellanos: I'm surprised. [laughter]

Dr. McAneny: I would like to make a recommendation that PPAC recommends that CMS not institute the 4.3% decrease in the fee schedule conversion factor, but instead use the MedPAC recommendation of the 2.7% increase while they're working for an SGR fix.

Dr. Castellanos: Is there any discussion? [laughter] Are there any cheers? [laughter] I'll call for a vote all in favor?

[Ayes]

[inaudible question]

Dr. McAneny: PPAC recommends that CMS not institute the 4.3% decrease in the fee schedule conversion factor, but instead use the MedPAC recommendation of a 2.7% increase while they're working for an SGR fix. Isn't it 7 from MedPAC? I can look it up, but I think that's right.

Dr. Castellanos: Would you read that back to us, please?

Ms. Trevas: PPAC recommends that CMS not institute the 4.3% decrease in the Physician Fee Schedule conversion factor, but instead use the MedPAC recommendation of the 2.7% increase, while working towards fixing the sustainable growth rate.

Dr. Castellanos: Are there any additions? Doctor?

Dr. Przyblski: I think we all agree with the sentiment, but is that something that can be done, and if it can't be done, is it just giving you one more source of our dislike with what's happening?

Dr. McAneny: Yes.

Dr. Urata: Yes.

Dr. Przyblski: That I understand. Can we do something a little bit more productive? We heard a little bit earlier about lunch that taking drugs out of the formula is something that's still being looked at. We've been talking about this for 2 years. Can we create a time limited response, either yes or no, you can or can't do it administratively by a certain date? And I don't know if we heard at lunch that that's planned for October 31st, I thought I heard that in between the words, but I'm not sure. Could our recommendation also include that we would like a response as to whether that could be administratively done by a certain date?

Dr. Castellanos: I'd like that as a second recommendation if that would be OK? We have a motion on the floor, I'll call the question. All in favor?

[Ayes]

Dr. Castellanos: Opposed? Greg do you have another motion you'd like to make?

Dr. Przyblski: My recommendation would be that PPAC recommends that CMS provide us with a definitive response as to whether drugs can be removed administratively by, and I'm open to suggestions as to a reasonable date given that this has been an ongoing issue.

Dr. Castellanos: Can I change that to "incident to" drugs, so it's clarified?

Dr. Przyblski: Yes.

Dr. Grimm: By next meeting?

Dr. Przyblski: By next meeting's fine with me.

Dr. McAneny: And you did have the retrospectively in there?

Dr. Przyblski: I consider that exceedingly friendly.

Dr. Castellanos: Dana can you repeat that please?

Ms. Trevas: The Council recommends that CMS provide PPAC with a response by the next PPAC meeting as to whether incident to drugs can be removed from the SGR retrospectively using an administrative methodology?

Dr. Castellanos: Did you put the time limit in there? Maybe you did—

Dr. Przyblski: By the next meeting.

Dr. Castellanos: Can you put by December 5, 2005? Could you read it once more time, please?

Ms. Trevas: The Council recommends that CMS provide PPAC with a response by December 5, 2005 as to whether incident to drugs can be removed from the SGR retrospectively using an administrative methodology.

Dr. Castellanos: Is there any further discussion? I'll call the question, all in favor?

Dr. Grimm: Before you go forward, does that statement imply if the answer is no, retrospectively then the simple answer can be no but it can be done from this day on, or should it be broader than that? Meaning that is what we would like is retrospectively, but let's say it can only be done from '98 on. Or 2000 on, or 2002 on, I can see a response being no we can't do it retrospectively.

Dr. Castellanos: I would assume that CMS will comment on that?

Mr. Kuhn: Well, as you heard from Steve, we have people asking us for comments for the Proposed Regulation, and hopefully we'll have a chance to respond to that regulation. So I think we could respond both retrospectively as well as prospectively.

Dr. Castellanos: So I'll call the question. All in favor?

[Ayes]

Dr. Castellanos: Opposed? Is there any other discussion, or questions, or motions that would like to be made at this time? Steve we certainly appreciate it. We missed a lot, we appreciate your being here. We recognize you are the messengers [laughter] and we certainly your being here. Thank you.

Mr. Phillips: Thank you.

Dr. Castellanos: We're running a little behind on the schedule, but I think we can take a 10-minute break and meet here.

Dr. McAneny: He had something to say.

Mr. Hart: I was going to do the outpatient.

Dr. Castellanos: Oh, I apologize. I thought you were finished. Excuse me.

[chat]

Dr. Castellanos: I have already tried to short change Mr. Hart. So let's see if we can get started. Mr. Hart, we've already introduced you before. And I apologize for cutting you short. If you could start right away.

Mr. Hart: OK, well, thank you very much. I guess it's worth observing at the outset that the Outpatient Prospective Payment System was implemented in August of 2000, which makes us 5 years old this month.

Dr. McAneny: Happy Birthday.

Mr. Hart: Thank you very much. I didn't bring any cake or candles. I don't know if payment systems have life cycles, but I suppose that 5 years means while we're not as grown up as some of our siblings systems, we're at least beyond the toddler stage. And thank goodness, well beyond the terrible 2s as well. This year, we estimate that we're paying about $25 or $26 billion dollars to hospitals through the Outpatient Prospective Payment System, with the changes that we proposed in our Proposed Rule last month, we expect the average payment rate will go up about 1.9% and taking into consideration other changes, volume changes, in particular, we expect payments in the aggregate will go up a little over 5%. I should say that the Proposed Rule went on display last month on the 18th. The comment period lasts until September 16th, and we of course always plan to publish our Final Rule by November 1st of every year. And as Steve said, with regard to the Physician rule, we very much encourage formal comments so that we can get them into the record and make formal responses to them in the Final Rule.

I just want to touch on a few of the highlights in this year's proposed rule as far as policy initiative, policy proposals that we're making. And in particular, the big one is our proposals with regard to Part B drugs, biologicals, and radio pharmaceuticals. Both with respect with new way to pay for the acquisition costs of the drugs in the hospital outpatient department, and a proposal for a brand new separate payment for pharmacy overhead costs. I also want to say something about proposed new adjustment for some rural hospitals under the system, and the final topic, which Steve already has covered pretty well, because our proposal's very parallel to theirs in the physician side, multiple imaging procedure discounting.

This year we think we're paying about $2 billion mostly for oncology and other injectable drugs in the hospital outpatient department, and under an MMA provision, those prices have been based on a percentage of average wholesale price. I don't think I need to review for anyone here the issues with regard to the use of average wholesale price. The Medicare Modernization Act called them in 2006 and beyond for the Secretary to pay for drugs based on average acquisition cost. And they also required us in doing to take into account a study that the Congress mandated the GAO to conduct of those costs. The MMA in addition to that, gave us the permission, gave us the authority to determine an additional payment amount for drug overhead costs in the hospital outpatient departments. And similarly, directed us to take into account a MedPAC study of those costs and we've done all that. In our proposal, after considering a number of data sources on acquisition costs, our proposal is to pay hospitals the average sales price plus 6% for those costs. The average sales price of course is now being reported for Part B drug and physician offices by the manufacturer, so we have the data on that coming in quarterly. We had several sources of data to work with, but we thought none of them quite in and of itself gave us a fix on those price, and taking everything into consideration, we think ASP plus 6 is the best proxy for it. It's pretty consistent with what the GAO survey data came in with and of course it is the same rate that we pay for those drugs in the physician offices. And it's worth nothing, of course, it's well below the current payments, which are running about the AWP based payments, are running about ASP plus 22%.

As far as pharmacy overhead costs concern, our proposal is to create three new payment categories and to begin collecting data on those through claims over the next three years so that we can set relative weights for those for 2008. The three categories will be oral drugs, cytotoxic injections and infusions, and non-cytotoxic injections and infusions. And in the interim when we're collecting the data and preparing to be able to set relative weights for those three new categories, we propose to pay an additional 2% of ASP over the drug acquisition cost payment to cover pharmacy overhead. So for the next two years, our proposal is that the total payment for drugs will be ASP plus 6, which represents the acquisition cost, an additional 2% for overhead, for ASP plus 8 overall.

radio pharmaceuticals pose some particularly difficult challenges in this regard. As I'm sure all of you know, they're rather unique distribution and production systems for radio pharmaceuticals and also the manufacturers have not be required to submit ASP data up to this point because they've been exempted

from ASP payment on the physician office side. So for this year, we propose that we would begin to collect that data from the radio pharmaceuticals manufacturers in 2006, hopefully for use in 2007 when [inaudible] actually set the payment rates. And in the interim, we're going to adopt a system of applying the hospital's cost-to-charge ratio to the charges for radio pharmaceuticals on the claims as an interim payment level. And of course we seek comment on both the radio pharmaceutical overhead categories, and we're also seeking very specific comment on all the issues regarding appropriate payment for radio pharmaceuticals.

In the interest of time, I'll skip over this one. Briefly, we've had a sort of a special payment for Aranesp and Procrit for the last few years based on a conversion factor between the two, and with the proposed transition to ASP, we think we can put that behind us and turn to market prices for those drugs as well.

We're all hospitals. There is currently, expiring at the end of this year, a special hold harmless provision for rural, sole community hospitals and small rural hospitals. Specifically, they are held harmless to the payments they received prior to OPPS in 2000. That provision expires at the end of this year, and the MMA instructed us to look into the cost for rural hospitals, as compared to urban hospitals, and if appropriate, if cost differences showed up in our study, to propose an appropriate payment adjustment for those hospitals. We did do regression analyses, comparing the costs of urban to rural hospitals, and looking at various subcategories of rural hospitals. And we did find, overall, a different between urban and rurals, but we also found when you broke it down into the categories, that all the differences accounted for by rural sole community hospitals, so therefore our proposal in the rule is for a payment adjustment of 6.6% just for the rural sole community hospitals. And we do present our analysis, and the rule of course we'll continue to study it and we hope and expect comment on that before we finalize it.

Final issue of course is the multiple imaging procedure discounting, and of course Steve has described this in some detail on the physician side. Our proposal is very much parallel to theirs. We use the same 11 families based on imaging and contiguous body area, and we're proposing the same level of reduction when multiple imaging are done in the same family to pay 50% for the second and subsequent one. And unlike in their side of course, there's no split in the payments, not applying to one part of the payment and not the other. It's for our whole payment.

I think the only other thing worth mentioning at this time is that since we published the Proposed Rule, we did find a couple of technical errors in the numbers that we produced. We made a technical error, and used the wrong rural adjustment. We used 6.4% instead of 6.2 and running our numbers completely inadvertent mistake. We also had a couple technical errors and how we accounted for aggregate drug prices. So we had to run all the numbers again. Some weeks ago we posted the updated files, on the Internet. They've been available to everybody on our website and as of last Friday, the formal correction notice went on display at the *Federal Register* and the published version I believe will be available in a few days for everyone to refer to. The upshot, I hope was the good news is all the rates went up .4% because of the errors we made. So there was no harm to anyone.

Dr. Castellanos: Thank you, Mr. Hart. Dr. Hambrick, did you have any comments you wanted to make?

Dr. Hambrick: No. Thank you.

Dr. Castellanos: Does Council have any questions for Mr. Hart?

Dr. McAneny: I wouldn't want to let you down. Just a note that once again, the Hospital Outpatient Prospective Payment System gets an automatic 1.9% increase, which they seem to be able to roll on year after year because they are not under a system that is a zero sum game like the SGR is. But I'm impressed that the hospital pharmacy requires an extra 2% over average sales price, that my pharmacy to deliver in my office somehow does not need. We have already passed a recommendation to add that 2% for the outpatient side as well, thinking what's good for the goose might be good for the gander. And that it ought to be equitable all along, because either the only thing we can assume from this, is either because the hospitals are so inefficient that they cost them more to deliver the same service that we're giving, or that it would be a discriminatory thing, trying to push patients to the hospital outpatient setting, which is less efficient and kind of makes no sense. So I just would like to make you aware that we did request that that same 2% over ASP that the hospital outpatient pharmacy gets should also go to the outpatient office pharmacy and see if you had any rationale for why there should perhaps be a difference in that reimbursement.

Mr. Hart: I really can't comment on the other side, except to say that of course we're carrying out a specific statutory authorization to do so. I don't know what the law prescribes on their side and whether

the discretion is there to do so. I can only say we had the authorization. We were told to look into it. We did to the best of our analysis of the data, at least over the next couple years 2% is what we came up with.

Mr. Kuhn: And that was also based upon a report we got from MedPAC, as well. That was also part of the statute required them to do the report.

Dr. McAneny: And similarly for the same radiopharmaceuticals that we give in our offices, they get the hospital cost-to-charge ratio, it would be nice to have a cost-to-charge ratio. I was interested to read in this that basically the least costly alternative for proposal is kind of how I think of it for Procrit versus Aranesp is basically going away. And I'm hoping that what this will mean is that least costly alternatives under the ASP system may be going away as well, at least in the hospital outpatient part. And that maybe that then will trend over to the office outpatient part. Any comments on that?

Mr. Hart: I can't comment beyond saying we do think this is a good time to propose a move beyond that for Aranesp and Procrit, on our side. I really can't comment on the…

Dr. McAneny: No plans to do the same for Lupron and the other LHRH agonists.

Mr. Hart: On the Part B side, I mean, on the physician office side.

Dr. McAneny: No, I mean even on the, well take it a step at a time, that works. Even in the hospital outpatient side.

Mr. Hart: No specific plans at this time.

Dr. McAneny: OK.

Dr. Castellanos: Are there any other questions? Are there any recommendations we want to make at this time, that we have not previously made? Seeing none, again, I apologize again, Mr. Hart for cutting your short. And I appreciate your staying. And Dr. Hambrick I really appreciate you—I gave you a chance at least. [laughter]

Mr. Hart: Steve and I were actually saying that to each other.

Dr. Castellanos: Excuse me, we do have one recommendation.

Dr. McAneny: And that was sort of going on to what Greg was alluding to earlier with the new practice expense relative value units, that PPAC recommends in order for us to be able to do what Greg suggested and evaluate those that CMS would provide examples of how the new values are calculated and the actual new practice expense values for each code in addition to the values for the first year of the

transition, the practice expense per hour and the source of the data per specialty and then the budget neutrality adjustor.

Dr. Castellanos: Is there any discussion on that motion?

Dr. Przyblski: I would add if it would be acceptable, an impact by specialty of what those changes would be when we looked at for example, changes in the malpractice RVUs, we would get a table that looked at the impact per specialty of a change in methodology. And the RUC frequently asks that of CMS. If you're going to make a change, can we see how it's going to affect each of the specialties by doing so, so I would add that bullet point, and also a second sentence that would request that this data is provided to us prior to implementation of such a change and with sufficient time for CMS to consider alternative recommendations for the change is implemented.

Dr. Castellanos: Is there any further discussion? Do you accept that?

Dr. McAneny: Yes.

Dr. Castellanos: Dana, we're going to have to ask you to repeat all that. [laughter]

Ms. Trevas: To facilitate the medical community's review of the new practice expense relative value units, the Council recommends that CMS provide to PPAC, examples of how the new values were calculated and the actual new practice expense values for each code, in addition to the values for the first year of the transition, which currently are included in the Proposed Rule, the practice expense per hour and source of the data for each specialty, and the budget neutrality adjustor applied at the end of the process, as well as the impact by specialty of the changes, and provide all of this prior to implementation and with sufficient time to consider alternatives.

Dr. Castellanos: Is that acceptable? Are there any questions on that motion. Seeing none, hearing none, all in favor?

[Ayes]

Dr. Castellanos: Opposed. Are there any other motions? Again, thank you Mr. Hart and Dr. Hambrick. We certainly appreciate your being here for that extended period of time. Thank you.

<u>Alliance for Cardiac Care Excellence Program</u>

Dr. Castellanos: The Alliance for Cardiac Care Excellence Program, again we're focusing once again on the quality measures. I'd like to welcome Dr. David Nilasena. Dr. Nilasena joins us today all the

way from CMS Dallas Regional Office, where he's the Chief Medical Officer. He's been actively involved in the QIO program since 1995 and was the CMS Task Leader for a National Quality Improvements for AMI and Heart Failure. His presentation will provide an overview of the alliance for cardiac care excellence. Dr. Nilasena.

Dr. Nilasena: Thank you. And good afternoon. I've been asked to give you a summary of the Alliance for Cardiac Care Excellence. And after hearing the earlier proceedings of the Council, I'm very thankful that mine is not a very technical presentation. I'm also thankful it has nothing to do with regulations. And in fact, it is not strictly a CMS initiative. [laughter] It's a joint initiative. So I have lots of ways to deflect any questions that you may have. [laughter]

I'll start by giving you a little bit of background about ACCE. Giving you a summary of the ACE activities and its current members. I'll describe a little bit about the current ACE organizational structure, and give you sort of a sneak preview of the draft ACE goals that were recently brought closer to finalization last month, and then just talk briefly about future plans for ACE and entertain any questions you may have.

By way of background, this originated from a group called the Quality Improvement Support Collaborative, on the next slide I'll show you the membership of that. But it was a group of national organizations that were interested in identifying ways of developing common messages around primarily health care quality efforts. Their early work was focused on diabetes measures and as they began to look for a new activity that was a little bit more broad ranging, they saw what was going on with the SCIP initiative that you heard a little bit about this morning, and thought it might be good model after some of the successes that SCIP had achieved early on. But they felt that cardiovascular care was an appropriate topic to select for their first sort of broad initiative, primarily because cardiovascular disease is very prevalent. It's a major cause of morbidity and mortality and health care spending, and also in terms of quality, there had been a lot of work done in the quality arena for cardiovascular disease. So after that initial decision was made, it became obvious to the QISC group that in order for any large scale cardiovascular initiate to be successful, we would need the help of the American College of Cardiology and the American Heart Association. And so they were recruited to become founding members of the initial group. So this is what we call the founding partners of ACCE. You'll see ACC and AHA on the list. The

other agencies on this list are the original members of what was the QISC group. And this group, after having a few meetings to sort of brainstorm what this initiative would look like, issued a joint invitation to a select group of agencies that they thought might be interested in a large-scale cardiovascular initiative. The invitation looked something like that, and I think it really captures what we were trying to accomplish with ACE at the beginning. We wanted to have each organization think about their individual missions and how we can align the missions of a large number of organizations who basically were trying to do the same but in slightly different ways. And so if we could get them to align their individuals missions and to define actionable, measurable concrete health system goals, we thought that we could be successful, because these goals could be accomplished if we worked together. But could not be accomplished if we worked individually. So the founding partners issued this invitation. We held our first meeting in January of this year so we are relatively new initiative compared to SCIP. I was hosted by the ACC at their Heart House, and we had 33 organizations attend that first meeting. Since it was a new initiative, the main purpose of that meeting was to introduce the organizations to the idea to get their initial commitment and to begin to formulate goals. Actually, going into that meeting, we had the idea that we would formulate a single goal. But as we got into the meeting, it became obvious that that wasn't quite as easy as they had done with SCIP. So these next 2 slides show you the current ACE member organizations. It does not include the founding partners that I showed on the earlier slide. But as you can see, primarily, organizations that are interested in cardiovascular disease, cardiovascular treatment, but we also identified some key, non-cardiac specific organizations that we thought would be important for this initial meeting. Next slide continues that list and at the very bottom, the Veterans Health Administration actually was a late addition. They weren't at the initial meeting, but they were recently added.

So after that first meeting, a couple of things came out of it. The first was we crafted this statement of intention that you can read for yourself, and it basically reiterates some of the things that were mentioned in the invitation. That we wanted to come together to create shared goals. We wanted to have commitment to achieve those goals, and the last sentence, I think, is important. That these goals would span inpatient care, transitional care, preventive and physician office care. So it wasn't just a single setting, which is in terms of quality improvement efforts has been the case for a lot of conditions, including cardiovascular care. So just the key elements from that statement are that we would develop common goals and a shared

vision. We would focus the existing efforts of each member organization and try to align those efforts. We wanted to create a sense of energy and collaboration. Also a sense of urgency, to getting this carried out. And importantly, we didn't want this to be just another initiative that created new measures and new projects that was just going to add to all of the other things that were going on. So we wanted this to actually try to reduce that confusion and burden rather than adding to it. We came up with this little heart model to display. Some of the discussion that took place at the first meeting was centered around goals that focused on four areas. Hospital health care systems and payers, and clinicians were sort of obvious targets, but also several of the groups identified correctly the importance of patients' families and communities, in setting goals, and then finally this category we call the National Drivers of Quality. We're sort of organizations that don't directly delivery health care, they don't directly receive health care, but they're very influential in the health care system. And that includes CMS and the joint commission and other sorts of regulatory organizations.

So based on that structure and that discussion. We're getting kind into the organization structure of ACE now. We've assembled into four work groups. Each work group can have members from any of the 33 organizations, based on their interest. The idea behind the work groups is they would continue to work on defining the goals and discussing the measures for those goals, and also discussing ways to best market and advertise the goals. We also have a steering group called the Leap Team, which again, any of the member organizations can participate in the leap team, and this is to deal with situations that require non administrative decision making activities. So they're not focused on any of the particular work groups, but it's an overall ACE organizational activity. We've established an intra-net site, which all of the ACE organizational members have access to. And it's our primary way of exchanging information and creating draft documents and draft goals and communicating with each other. It's also a way that we can store the information created by the group. And so that's sort of after the first meeting, those were the things that were developed.

We had our second in person meeting last month. Again, hosted by the ACC. This time, 26 of the original members were able to attend, and our goal for that meeting was to nail down the goals for each of the work groups and to develop specific action plans. As you'll see in a minute, we weren't able to completely nail down the goals, although we did make some progress, but we do have a lot more activity in

each of the member organizations in working towards those goals. So these are some examples of the draft goals. They're still draft. And for some of them it will be obvious why they're still draft. It'll give you a sense of the type of discussion that the ACE members have been having. And the direction of the goals that we're trying to set. So for the patients' families and communities work group, the first goal is to have the defect rate for screening. For fasting lipid profiles, blood pressure and fasting glucose, so these are sort of preventive measures for cardiovascular care. Another of the goals is to encourage collaboration and to share promising practices that promote cardiovascular disease risk awareness and prevention. The clinicians work group is focusing on the educational process and incorporating quality improvement into all levels of health care education. They began by just thinking about physician, but now they're beginning to expand into other health care providers. And interestingly, one of the members of ACE is from the American Board of Internal Medicine. And they have plans to actually build this into the certification, the board certification process. So we're excited that they're willing to move in that direction. For the national drivers of quality, their goal is centered around aligning and publicizing their joint efforts around evidence-based clinical measures for cardiovascular care. And for the hospital and health care group, their first goal is centered around what's called the quality discharge, and you'll see the elements of that discharge listed in A through E. And the idea is that in the hospital setting, that 95% of hospitals would receive the contents of this quality discharge, and that 90% of patients would ultimately be discharged using such a tool. Another goal for the hospital work group has to do with what we call appropriate care. And the goal pertains to hospitals measuring the level of appropriate care and then also achieving certain targets for appropriate care for heart failure and AMI patients. On this said, it says Appropriate care is defined by the National Drivers of Quality Group. At our July meeting, we decided to adopt the methodology that's proposed in the CMS QIO Scope of Work, which is basically looking at all of the indicators for that patient for which they are a candidate and seeing if they passed all of the measures. And so if they passed them all, then that's considered appropriate care. If there's any one that they're eligible for and don't pass, that's not considered. So that was the definition adopted by this group.

So in terms of the future, our immediate need for ACE is to establish an ongoing way of supporting the group. Up to the end of last month, it was supported as part of a subcontract of a QIO contractor, paid for by CMS. And of course some of the other founding partners contributed to the face to

face meetings, particularly the American College of Cardiology. But at the end of July, that contract expired and was not renewed, and so we're sort of scrambling now to continue the support and the momentum that we've gained in the first two meetings. Once we've established that, our plan is to finalize and publicize the goals, to follow up with each of the member organizations on their action plans, to enlist additional organizations to the ACE initiative, and to track our progress towards these goals. And we're hoping if we can have some initial success with ACE we can continue to set goals in the future and this will be an ongoing sort of process for cardiovascular health. So that's all I have. I'll entertain any questions, or comments, or recommendations.

Dr. Castellanos: Are there any questions from the Council? I have two questions. One is I showed this to some of my colleagues in my community. They were kind of surprised how quickly you were really jumping on this. I heard from Ken this morning that some of the Pay for Performance initiatives are going to be hopefully implemented starting next year. What's the plan here? Is there anything as far as—I noticed you had a time table, and the only work group that you didn't have a time table time on what the clinicians.

Dr. Nilasena: Right. As I mentioned, these are, although our plan was to finalize these goals last month, actually I don't think any of them got completely finalized, and some of the dates embedded in these goals were from the original draft. And as we get closer to the end of 2005, having a target for December 2005 makes less and less sense for some of these goals. So those will certainly change. But in terms of the question about Pay for Performance, as I mentioned, this is not a CMS initiative. This is an initiative of which CMS is a part, we're one of ten founding partners, and one of 34 organizations. So in terms of ACE as a group, they don't have any sort of power to do Pay for Performance as their group. Now there are individual members within ACE that that may be part of it, and certainly Pay for Performance would be one vehicle by which we could incentivize progress towards these goals. But I don't think that that is within the jurisdiction of the ACE group to make decisions about. So the idea behind ACE is that they set the targets for cardiovascular health, and each member organization figures out how they can contribute to moving towards that target. So from a CMS perspective, obviously under the current administration, Pay for Performance is high on the radar screen, and so that would be a logical target for one way to move towards the goal. But that's not really part of ACE.

Dr. Leggett: I have a couple comments. As I look at this product, it's not largely dissimilar from the American Heart Association's Get with the Guideline effort to address the same issues that you're raising about quality care, discharge, adherence to guidelines for heart failure, for ischemic heart disease, etc. And the partnership that's present is wonderful on paper. When I look at your ACE work group section, and the bullet points that you have under there, I'd like to raise one issue that I think is largely ignored in this whole process. And that is the following: If you are familiar with the Institute of Medicine Report from about 3 years ago, which addressed the issue of access to quality cardiovascular care, it was unequivocal that there is a disparity in access to care in this country, particularly among minority patients in access to cardiac procedures, cardiac surgery, etc., etc., etc. And I think to have a work group that does not have a bullet point to address the reduction in this disparity in access to cardiovascular care, when on the face, you are simultaneously putting out a product that says that we're trying to make sure that the quality of care is uniformly distributed, when we know from factual evidence that it's not, I think one of the inherent points has to be in the process of addressing this issue, you've got to address this disparity issue. I mean you've got to do it. Now, the question becomes what should CMS's role be in that? And for me, since CMS carries a big stick in many instances, I'd like to see CMS take a very active role in helping to address this disparity issue as it relates to the distribution of quality care in this country, because it is not uniform, and it's not any secret that it's not uniform. So under this work group session, I think the omission of that, because on the face, if you look at the country as a whole, what we see because there is a variety of populations here, is cardiovascular care looks like it's improving. But when you fractionate it down among ethnic groups, Hispanics, African Americans, their cardiovascular is skyrocketing to the moon in the wrong direction and getting worse. But when you put all the numbers together, America looks like it's getting healthier, when in fact ethnically it is not. So CMS has to take some active role, in my view, if you're going to put together an alliance, with all the major organizations to address this access, qualitative issue. Then we've really got to address in a real way and not sort of this surface way that makes it look like all things area getting better, when in fact for certain groups nothing is changing. So if some point, if we were making recommendations, as it relates to this, and I haven't formulated this in any particular jargon, but I think one of the recommendations should be that CMS should assume a very active role in trying to address or create, or even establish modalities that can monitor whether or not a reduction in this disparity is

occurring, so that access to quality cardiovascular care is actually being achieved in this country, even as it relates to this particular product.

Dr. Nilasena: Yes, and I certainly can't disagree with that. As I pointed out at the beginning, this is not a CMS initiative. And the contents of the ACE recommendations emerge from the entire group. It is surprising and I guess I hadn't actually thought about it until you just brought it up, it's surprising that that didn't emerge in the discussion among the 34 member organizations.

Dr. Leggett: It's not surprising to me, because as a prior President of the largest region of the American Heart Association in this country, frankly, people were oblivious and they're oblivious because the majority population is not affected by it. But if you ask the American Indian, or if you ask the Hispanic population, or if you ask African Americans who have disparate care, then it's a paramount issue. So when you ask all of these organization on face value, they see, they look at global numbers, and the global numbers say things are getting better. So it's not particularly surprising, it's just being ignored. And I don't know that they wake up in the morning saying Let's ignore certain people. I don't believe that. What I believe is that it looks like it's getting better, enough voices are not being raised to address the area where it's not getting better, so they focus on what's getting better and they perpetuate or create guidelines to address that side of the question. So I guess what I'm asking you to do as one of the members and someone who is presenting to us is take this back to the group. Make some effort to have this particular issue included in one of their work shop points, and if it can't be included, come back to us with some reason why they felt like it wasn't necessary to include it.

Dr. Nilasena: Right.

Dr. Leggett: And I think that lack of inclusion cannot possibly happen if it is presented correctly.

Dr. Nilasena: Right.

Dr. Castellanos: Chris, would you like to make a motion or a recommendation?

Dr. Nilasena: While he's writing it, I might add that I mentioned that one of our future plans is to recruit additional organizations. And so one way that we might also address that is by including organizations that represent the groups for which there is a disparity. We already have plans to include the Indian Health Service, but I'm sure there are a large number of other organizations that could contribute and make sure that that isn't lost in future discussions.

Dr. Leggett: If I could make this recommendation: PPAC recommends that CMS assume an active role to ensure that the ACE project works to reduce cardiovascular health disparities and access to quality cardiovascular care.

Dr. Castellanos: Dana, could you repeat that for us?

Ms. Trevas: PPAC recommends that CMS assume an active role to ensure that the ACE project works to reduce disparities and ensure access to high quality cardiac care.

Dr. Castellanos: I think we need to put minorities in there.

Ms. Trevas: The Panel recommends that CMS assume an active role to ensure that the ACE project works to reduce health disparities among minorities and ensure access to high quality cardiac care.

Dr. Leggett: So, recommend that CMS assume an active role to ensure that the ACE project works to reduce cardiovascular health disparities among minorities, and increase their access to high quality cardiovascular care.

Dr. Castellanos: One more time, please.

Ms. Trevas: The Panel recommends that CMS assume an active role to ensure that the ACE project works to reduce cardiovascular health disparities among minorities, and increase their access to high quality cardiovascular care.

Dr. Castellanos: Is there any further discussion? Call the question. All in favor?

[Ayes]

Dr. Castellanos: Opposed? Are there any other questions?

Dr. McAneny: I have a quick question. Is there any data collection component associated with this, and if so what is that data going to get used for?

Dr. Nilasena: Yes, the ultimate plan is for all of the goals that there would be some way of tracking and measuring progress towards that. The only one that we have sort of a specific data source identified for is the Appropriate Care Goal. And our plan is to use the measure of data that's being submitting to CMS on the Joint Commission for their two programs. And analyze that data at the hospital level for MI and heart failure, and get the appropriate care rates using that data.

Dr. Castellanos: Are there any other questions? Dr. Nilasena, we appreciate your traveling here from Washington and taking the time away from your busy schedule. From Dallas.

National Provider Outreach and Implementation

Dr. Castellanos: OK, our next discussion is going to be on the National Provider Identifier, or NPI. Valerie Hart and Debbie Auerbach are here to share their expertise and update us on the outreach efforts and the implementation as they relate to NPI. Ms. Hart is currently the Director of the Division of Provider Information, Planning and Development at CMS. She is responsible for the management oversight of ensuring that CMS meets the national educational needs of the Medicare Fee for Service providers. Valerie has been at CMS since June of 1989, and has worked in various capacities throughout the agency, gaining experience in both the substantive and operational policy areas. Deborah Auerbach, or Debbie, joined CMS exactly a year ago, on August 23, 2004. Debbie has 25 plus years in health care claims systems, starting as a cobalt programmer with Blue Cross Blue Shield in South Carolina. And eventually serving as Vice President of Operations at a Maryland-based health care software consulting firm. She is the overall systems lead for the NPI initiative. Valerie and Debbie would like us to consider the following questions as they present their data today: 1) are there other effective ways to directly reach physicians with our NPI message and content; 2) health care providers have been encouraged to make their NPI available to entities that need them to conduct standard transactions, how do you plan to share the NPI information? Debbie and Valerie, we welcome you here today.

Ms. Hart: Thank you. Thank you for giving us the time to come down and update you on CMS's NPI activities. I'm going to first update you on the outreach activities that CMS has been conducting, both for all providers and then also for the Medicare providers. And to that end, we'll be talking about the NPI outreach subgroup formation and how we are trying to get one consistent message that comes from the top and goes down to the lowest grass roots possible. We'll be talking about the outreach data that we're collecting to ensure that the information does flow all the way down. Some of the hot topics, such as data dissemination, and also some key websites that can give you some additional information on NPI.

Now, I know that you're aware of the NPI mandate from the HIPAA legislation. I know that the last meeting that occurred, there were actually some physicians here who went on line and got your NPI, and basically all covered health care providers are required to have an NPI. Both Medicare and non Medicare providers by May of 2007, with the exception of small health plans which must have them and be using them by 2008. And the small health plans are defined as health plans with revenue of less than $5

million per year. And just to give you an idea of this past Friday, I was told that over 101,000 providers and organizations have applied for an NPI. The majority of them have been through the online process, and the top 5 states that are leading in the NPI enumeration are currently Texas, Pennsylvania, New York, California, and Florida. Not surprisingly. Given the scope of our audience, at CMS, the all health care providers, CMS needed to make sure that our communication process was tightly controlled with the top down approach. To accomplish this, CMS chartered an agency-wide outreach committee to develop a consistent and coordinated outreach campaign to all sectors of the health care industry. Members of this committee have communication channels to distinct constituencies, such as private insurers, national partners, such as the work group for electronic data interchange or WEDI, and the American Health Information Management Association, state survey agencies, state Medicaid agencies, the Fee for Service and Managed Care Medicare Providers, researchers and basically others involved in health care. The committee membership also includes individuals who are responsible for outreach at the regional and local levels. The CMS regional offices have relationships with the state and local medical societies, and state chapters of national associations. Additionally, the Committee's responsible for distributing information to Medicare contractors who have relationships with the individual Medicare providers, and who account for more than 1 million health care providers in the US. Using this network approach, we believe the composition of the agency-wide committee and its constituencies will allow us to reach all health care provider communities.

And for those who respond better to graphics rather than a list of text, we have this graphic which illustrates the flow of information. Basically, when we get new NPI information that needs to be disseminated, it will go to both the CMS Policy & Operational Experts, in addition to the NPI Outreach Sub Group Chair, who is Jerry Nicholson, and they'll work together to make sure that they get a message that CMS wants to distribute consistently on a national basis. That will then go down to the NPI subgroup members, who will then distribute it to their particular constituencies. Through this method, it's hoped that as you can see at the bottom, the individual providers will ultimately end up with this information.

The next slide just shows a little example of how this would work. For example, if the message is the release of Medicare implementation data, this would go down to the provider communications group, subgroup member, since that person would be responsible for the Fee for Service Medicare providers. And

then on the right, you see various ways that we would get that information out, including the creation of a MedLearn Matters article, various provider list serves. We work with provider partnerships, who are contacts at national associations, and distribute it to the regional offices and also the Medicare contractors.

To ensure that we are in fact conducting the activities and that the information is reaching the appropriate audience, the outreach subgroup compiles data on a quarterly basis and submits it to the CMS Chief Operating Officer. This just gives you some information that we've had for the most recent quarter that we've conducted. To show you that we've had extensive external outreach events, and this includes the first NPI Roundtable. There will be another NPI Roundtable Call on September 14th which is open to the public. We use a lot of website communications, emails, list serves, it's a good way to reach out to a broad audience. We use the web a lot to post highlights and we have several websites that are available, that I'll talk about in a minute. And we have educational products which do include the MedLearn Matters articles. We have frequently asked questions, a web tutorial that is on the CMS website, and we enlist the CMS Medicare contractors to also perform a lot of activities, since as I said before, they do, they are the ones that reach the individual providers.

The key websites that are currently available is the National Plan and Provider Enumeration System. This is where providers would go to apply for their NPI, and we have on the CMS HIPAA website the latest news that's where you can access the viewlet that I mentioned, and the MedLearn Matters articles and soon we'll be coming out with an NPI website that is strictly for the Medicare Fee for Service providers and that will be off of the MedLearn website on the CMS website. Some of the hot topics that are currently under discussion, first of all, are the parts and subparts. Basically, CMS's position is that it's up to the health care organizations to determine what its subparts would be. However, CMS is working on a paper that will define subparts for the Medicare Program. This paper's currently in the clearance process, and will be released at a later date. I have to tell you all these issues and Debbie will probably talk more about that. It's stirring up a lot of discussion, so a lot of them are still being worked on and they will be released in a timely fashion. The electronic file interchange, or bulk enumeration, the NPPES system will accept bulk enumeration in the future. CMS once again is working on defining this process and developing a system that will accommodate bulk enumeration. And finally, with data dissemination, we expect to publish a proposed notice regarding CMS's approach to NPI data dissemination later this year. The

proposed approach will describe the data that CMS expects would be available from the NPPES in compliance with the provisions of the Privacy Act, the Freedom of Information Act, the Electronic Freedom of Information Act Amendments of 1996, and other applicable regulations and authorities. And this proposed notice will describe the data dissemination strategy and the processes that will be used. I have my question here, but I supposed that we'll wait until after Debbie does her presentation for that.

Ms. Auerbach: My name is Debbie Auerbach. I too am very happy to be here. I've made my year at CMS so I guess I'm officially kind of sort of off probation. I wanted to share with you today just a few of our plans for how we're going to roll out the implementation strategy for Fee for Service claims processing. And I have several slides to share with you. We're taking the process through a four-stage step.

Implementing NPI at CMS really is a major undertaking. It affects dozens and dozens of data bases, hundreds of systems across the agency. We are approaching it very much like the way the agency approached the Y2K initiative, but we also realize that this initiative is far more analytical than the Y2K was, which was primarily a mechanical exercise. We're not taking a big bang approach. We're not going to flip a switch and say on a certain day everything has to be NPI. We're gradually incrementally doing a plan to implement this initiative, and it's not a big bang approach. We hope to mitigate some of the risk by doing it this way. Valerie mentioned WEDI. We are working very closely with the WEDI group, that's the electronic data interchange work group. They're very prominent in this period of time, looking at a lot of NPI issues. They're writing white papers. They have a big brain truss really thinking all this stuff through, and they're really helping the industry as a whole to deal with NPIs. As I said in this slide, we're taking this process through three stages. Since I produced the slide, we're actually saying four stages. And I'll hit these stages as I go through it, but let me just what I'm heading for. Right now, in today's world, we only accept on a Medicare Fee for Service claim what we call the Legacy identifier, or the old provider number. Starting in January, which is stage 1, we will take the Legacy identifier, the old number, as well as the NPI, as long as you give us both. That way we'll be able to receive, accept both numbers in stage 1. In stage 2, we'll be able to accept the Legacy number, both, or just the NPI. So again, we're phasing it in slowly. And then by phase 3, we'll be able to receive, because of the legislation, only the NPI. I'll give you more details as we work through these slides. I'm going to set up a stage 4 simply because I need to have a special consideration for those small plans that Valerie mentioned, and give them an extra year for us to send them

both the Legacy number and the NPI. We will be introducing into our plan as most payers are, a crosswalk concept. So again I'll touch upon that a little bit more.

Just so we're all in the same page, when we talk about Legacy provider identifiers, those are those provider numbers that are assigned by the health care plans so that you can use your identifier in transactions that they require. They're often called the Legacy identifiers, and it's those numbers other than the NPI, other than the tax ID numbers. In terms of CMS, we deal with several different Legacy identifiers, including UPINs, which I'm sure all of you are aware of. The billing numbers or PENs, the supplier numbers, the NCPDP provider numbers, as well as the institutional numbers, or the OSCAR numbers. So we have several different kinds of Legacy identifiers that we have to fret about.

Like many providers, many health plans, CMS is endorsing the WEDI dual strategy. Are you familiar with that particular strategy that this work group is advocating? It's a methodology by which you can send both identifiers as soon as possible so that health plans can use the NPI if they're ready to use the NPI, or it can still use the Legacy identifier if they're not ready to use the NPI. So it's called a dual strategy, and we, CMS as a payer, is endorsing that plan as are most health plans, I think, across the industry. It really helps us to decouple changes between CMS when we're ready to use the NPI and when our trading partners are ready to use the NPI, and it's another great vehicle for capturing data so that we can see as claims come in, both the NPI, the new number, as well as the Legacy identifier, the old number, and use that in building our crosswalk.

So does it mean? It means as a receiver of claims, we'll be capable of receiving the NPI as a primary identifier, starting as early as January. The January 2006 release of our software in claims processing will allow both the identifier NPI as a primary and the Legacy as a secondary identifier. As a sender, we'll be able to send the NPI as a primary, and the Legacy identifier as a secondary identifier and all claims going to our trading partners. That, too, will kick in in January. As both the sender and the receiver, we will continue to rely on the Legacy numbers. We're not changing over systems to process with the NPI on a day one. We're using a crosswalk, but we'll use the old Legacy identifier, so that we can continue to process and pay your claims the way we have in the past few years.

I want to hit upon all the stages and then we'll be available for questions. Starting in January, and running through October the 1st of 2006, we'll be accepting claims with an NPI as long as you also send us

a Legacy identifier. So this when you'll be sending us both identifiers, and we will not reject claims that come in with an NPI, so long as you do give us that secondary Legacy identifier. We'll be editing the NPI simply to see if it looks like an NPI. It has to be 10 digits, it has to be numeric, it has to have a correct, valid checked digit, that's all the editing we can do in this particular period of time.

If an NPI is included on an inbound claim, it will also be reported on the electronic remittance that goes out on the back end. It will be sent as well to the COB trading partner, if an NPI comes in on the claim, we will pass it on to the trading partner on the back end. During stage 1, which is when we're doing the dual strategy, unfortunately the paper claims, which some of you may still be using a little bit, paper claims will not support that particular strategy so during this period of time from January to October of 2006, you're not to submit NPIs on paper claims, but instead to use your old Legacy identifiers.

Stage 2, we're going to implement in the October release of next year. With stage 2, the primary difference is we'll be implementing rolling out our provider crosswalk. So by that point in time, we will have built a crosswalk data base, and a crosswalk system that will walk an NPI that comes in on the claim, to the Legacy identifier that you have using in the past. So that will be in place by October of 2006. So if you send in the claim with an NPI and no Legacy identifier, we would hit the crosswalk, come back with the provider, the Legacy identifier, and use that Legacy identifier to do the adjudication of the claim and any other processing that had to happen. If the Legacy number cannot be located on the crosswalk, we would have to reject the claim, because we would not be in a position to adjudicate solely with the NPI in stage 2.

Stage 3 is the actual effective date of the legislation; May 23rd, 2007. We have to be fully ready, fully NPI compliant, so the Legacy identifiers can no longer be received, nor can they be sent to the large trading partners or on outbound transactions. This is the period of time when we would probably have to make some concessions to continue to send Legacy identifiers to the small plans, because they do have an extra calendar year to be in full compliance. So they'll have another year til 2008 to be ready for NPIs.

If you started to think about how you're going to build a crosswalk, or how your clearinghouses are going to build crosswalks, it's a fairly elaborate process because we're quickly learning that the way you're enumerating, the way the Final Rule allowed you to enumerate, it will not necessarily be a one to one relationship from the NPI to the Legacy identifier. In some cases, one NPI may map to multiple Legacy

identifiers. In other cases, many NPIs may map to the same Legacy identifier. So what we're learning is we have to figure out ways to identify the correct mapping based on the components and the data elements that come in on the face of the claim. Organizations, including CMS, are looking at various sources of data to try to determine the best way and best quality that we can put into our crosswalk. We're reliant on the NPPES data dissemination that Valerie spoke of. We know that if large entities do bulk enumeration, that is almost a self-fulfilling prophecy in that you get a crosswalk as you do your bulk enumeration. We know that many of you are coming up with data exchanges, ways that you would share your NPI information with other plans and clearinghouses, and we're going to be reliant on that claim data, because if we're collecting both identifiers for a period of time, we're going to use that as a data source to make sure that we are capturing that information for our crosswalk as well.

This is my question that I posed earlier. It's important that the crosswalk tables be as accurate and up to date as possible and that you make your NPI information available to entities that need them to conduct standard transactions. So the question is how do you plan to share your NPI information? Have you thought about how you might be doing that in your industry? In your business, over the next few years? Over the next 2 years. I mention these key websites. I put in here the WEDI website, because as I said, they have many white papers and quite a few articles that are very informative, quite useful. And then I also included the paper claim websites for both the professional as well as the institutional claims that are going to be released in revisions over the next couple of years.

Dr. Castellanos: Thank you for that presentation. Are there any questions from the Council members? Well, I have one, more of a clarification. Last meeting and we talked a little bit about it today, the bulk enumeration. I know there's one society that's hoping to be able to do that for the whole society. And I think you need to define what bulk is.

Ms. Hart: Actually, I looked into that, and organizations, there are no parameters on that really, organizations other that group practices, and health plans can be bulk enumerators. So the group and health plans were really listed as just examples. So it could be an association that could be a bulk enumerator.

Ms. Auerbach: There will be a process by which they will be certified as a bulk enumerator, and then they have to get authorizations from the providers on behalf of whom they're trying to enumerate. So there's a multi-step process that's being defined in this bulk enumeration policy that's being drafted back at

CMS. We do know that several societies are looking into that. I think a couple of state agencies are looking into bulk enumeration. And I know that some of the larger groups in general are looking at that process. Because of the fact that it's not completely defined yet, a lot of folks are holding back to decide how to enumerate, when to enumerate.

Dr. Castellanos: Are there any other questions, or recommendations from the Council? Well, we certainly appreciate both Valerie and Debbie for coming here today and we appreciate your interest.

Testimony

American Medical Association

Dr. Castellanos: There are two organizations that are going to be making presentations today. The American Medical Association, Dr. Ardis Hoven. I'm pleased to welcome Dr. Ardis Hoven from the American Medical Association. Dr. Hoven would like to discuss and address the Council with statements related to the Physician Fee Schedule, NPI Outreach, and implementation, and the Competitive Acquisition Program. The AMA's written testimony in its entirety can be found in Tab O in your briefing. And Dr. Hoven, I understand you used to sit up here a couple of years ago.

Dr. Hoven: Yes, I am a former member of PPAC. And I see some familiar faces around the room, and as I recall, we used to have some absolutely elegant lunches, with wonderful food and I suspect that still continues, does it not? Thank you very much. Mr. Chair and members of the Council, my name is Ardis Hoven and I'm an internal medicine and an infectious disease specialist in Lexington, Kentucky and a member of the Board of Trustees of the American Medical Association. The AMA appreciates the opportunity to present our views today on several critical issues. The proposed physician rule for 2006 is the first matter at hand and there are several issues I will raise in that connection. The Proposed Rule confirms that without intervention by the administration and Congress Medicare physician payments will be cut 4.3% in the year 2006. This is just the first in a series of cuts that are projected by the Medicare trustees over the next 6 years, totaling about 26%. This simply is not sustainable. CMS Administrator McClellan, as well as key leaders of Congress, have all publicly stated this same view. Physicians will not be able to absorb these cuts, and the AMA is concerned that as a result, physicians will be forced to limit services to their Medicare patients. This will cause a serious access problem that the AMA is working on with Congress and CMS to avoid before January 1 when the first round of cuts will kick in. As we advised

at the last PPAC meeting, a recent AMA survey indicates that if the projected cuts begin as scheduled, in 2006, more than a third of physicians plan to decrease the number of new Medicare patients they accept. More than half plan to defer the purchase of information technology. And a majority will be less likely to participate in the Medicare Advantage plan. The projected cuts are due to the fatally flawed Medicare Physician Payment Formula. The SGR must be replaced with a new formula that accurately reflects increases in the costs of practicing medicine, but it's an expensive undertaking for Congress. CMS can help make this happen, and here's how. First, CMS must immediately remove the cost of physician administered drugs from calculations of the SGR, retroactive to 1996. We appreciate that PPAC has previously make this recommendation to CMS and we urge PPAC to do so again for purposes of the 2006 Physician Payment Rule. CMS has the authority to retroactively remove drugs from the SGR. An analysis of this authority was set forth in a legal memo by Terry Coleman, a former acting General Counsel of HHS, as well as a former Chief Counsel and Deputy Administrator of HCFA. The AMA has previously provided this memo to CMS. House Ways & Means Chairman Thomas and Health Subcommittee Chairman Johnson, as well as Senate Finance Chairman Grassley, ranking member Baucus, and 87 additional senators recently sent written correspondence to CMS administrator McClellan and OMB Director Bolton requesting that drugs be removed from the SGR. Chairmen Thomas and Johnson also requested that CMS take steps to ensure that the SGR reflects the impact of national coverage decisions and government-induced increases. We urge PPAC to also make this recommendation to CMS for the 2006 payment rule. CMS has said that it would be very difficult to estimate any costs associated with national coverage decisions and that any adjustments would like have little affect on future updates, yet CMS already adjusts Medicare Advantage payments to account for national coverage decisions. So it is clearly able to estimate these costs. Indeed, in the Proposed Rule, CMS acknowledges that Medicare coverage of PET scans has increased dramatically since CMS initiated Medicare coverage in December 2000. CMS acknowledges that this volume growth and the costs associated with these types of national coverage expansions should be reflected in the SGR.

Turning now to other matters in the Proposed Rule: CMS announced its plan to revise the current methodology for establishing practice expense relative values for physician services. In doing so, CMS has accepted practice expense survey data submitted by a number of medical specialties. There would be four-year phase in of the new values, which, when fully implemented, would lead to significant pay changes for

some specialties. The medical community needs time to more closely review the values and overall impact of the proposal. The facilitate this review, the AMA urges PPAC to recommend that CMS provide the actually new practice expense values for each code. This would be on top of the values for the first year of the transition, which currently are included in the Proposed Rule. CMS should also provide examples of how the new RVUs were calculated. The physician rule also proposes to apply the current Stark physician self-referral ban to diagnostic and therapeutic nuclear medicine services. CMS has asked for public comment on this proposal. The AMA is very concerned about the potential for this proposal to disrupt patient care or limit access to these services. We urge CMS to give due consideration to the significant financial investment physicians have already made to provide these services to their patients. In my state, for example, a rural state, I fear and does the AMA, that the potential here is to cause significant difficult with access to care. Further, if CMS moves forward with this proposal, we believe that the Agency has the authority to implement a grandfather clause and would urge CMS to do so.

Next I will address concerns about the National Provider Identifier or the NPI. The AMA greatly appreciates the time and support we have received from CMS staff on NPI issues. We believe that a successful cost-effective and time implementation of the NPI is achievable. We have a number of recommendations in our written statement to achieve this goal, and we urge PPAC to make these recommendations to CMS. We have also heard anecdotally from physicians regarding concerns about online enrollment, as well as potential security hazards inherent in having so much information associated with an identifying number. We urge PPAC to make the recommendations in our written statement regarding these concerns. Also a significant number of physicians seem to remain uninformed about the NPI, and we encourage PPAC to recommend that CMS reach out, educate physicians and providers more aggressively. Finally, a word about CMS's Competitive Acquisition Program, the CAP. We are pleased that CMS favorably responded to a number of AMA concerns about the CAP in a recently issued Interim Final Rule. We will address ongoing concerns and our comments on the Rule, but we would like to highlight one in particular. We applaud CMS requiring vendors to create a process for helping beneficiaries who cannot afford their co-payments, but we have strong concerns that vendors ultimately will be allowed to refuse to dispense additional drugs through the end of the calendar year to patients who have not paid their co-insurance within certain time limits. Physicians may opt out of the particular drug category

involved if this situation occurs, yet allowing vendors to refuse to dispense the drugs, would have negative consequences for patients' health and would discourage physicians from participating in CAP at all. Thus we want to work further with CMS to address this potentially serious problem. Thank you again, and on behalf of the American Medical Association, we are delighted to be here and thank you for the opportunity of providing this information to you.

Dr. Castellanos: Dr. Hoven, thank you very much. Does anybody have any questions for Dr. Hoven.

Dr. McAneny: With the national provider identifier number, right now we have billing numbers and they're out there in the world, what is going to be different about this that makes it somehow more risky for that number to be accessible to other people. I don't get why this is…

Dr. Hoven: Apparently, there are some very serious concerns and again I can't speak to all the details and I'm sure our staff can get that, for you, but physicians particularly have raised concerns about access to this information. Simply because of the amount of data that has to be shared. So there are legitimate concerns about it. I think the protections have got to be looked at, and it's got to be balanced so that we achieve what we need to achieve with the NPI, but in fact that protection still exists.

Mr. Kuhn: I would just have to check with staff here, because that's the first I've heard that there are some concerns about the data. But we'll look into that.

Dr. Castellanos: Again, thank you, Dr. Hoven.

Dr. Hoven: Thank you all.

Dr. Castellanos: The Association of American Medical Colleges, on behalf of that organization, Dr. Albert Bothe will present his testimony next.

American Association of Medical Colleges

Dr. Bothe: Thank you, Dr. Castellanos. I realize I'm the only thing standing between you and adjournment, so I will be brief. [laughter] The AAMC appreciates the opportunity to comment on two particular issues in the Proposed Rule. The first, you've actually heard a lot about today. We agree that the SGR formula is problematic. The volatile and negative nature of it on physician payment certainly affects academic medical centers, we're on average 24% of the population served by group practices are Medicare beneficiaries. We would echo the sentiment that CMS should consider all its options in exercising its

administrative authority to mitigate the affects of SGR and specifically to consider removing the expenses for drugs covered under Part B.

The second major category we have not heard much about today and that's the Pay for Performance discussion in the Propose Rule. I have really three comments to make about that. In May, we recommended at this meeting, a number of design principles for inequality improvement or performance system. And we repeated those in the written testimony that was at your places on page 3 and 4. We believe those design considerations would ensure the best possible outcomes for patients, while at the same time being equitable and reasonable for physicians. So we encourage CMS as they move to Pay for Performance to incorporate these concepts. In a little more detail, we hope that CMS considers the potential burden on moderate to large physician groups. If large numbers of metrics must be introduced rapidly and simultaneously—earlier today, we heard 2 sets of performance process and outcome standards. If a large group is faced with administratively tracking, verifying, and reporting a large number of metrics all at once, it'll be a tremendous burden for these groups. So we suggest that CMS use its administrative authority to introduce these in a flexible manner to accommodate the varying structures of large groups.

And finally, we hope CMS will give careful consideration to the methodology to attribute to individual physicians or to groups, the care of patients, so that quality improvement and performance metrics are correctly assigned to those responsible for the particular delivery of care, so that we minimize the potential unintended consequences of duplicate unnecessary testing or avoid penalizing a provider who, in fact, is not responsible for that element of care.

The AAMC appreciates the opportunity to comment on these issues in the Propose Rule.

Dr. Castellanos: Dr. Bothe, we appreciate it. Does anyone have any questions for Dr. Bothe? Thank you for coming. Appreciate it. [chat] We're going to circulate the written recommendations that were made orally today.

Wrap Up/Recommendations

Mr. Kuhn: I think everybody has these recommendations that you made. Hopefully the reflect that what you all heard right back to you. I think if there's any kind of minor changes or tweaking, the record will be open so those could be wrapped up, but I think that capture the gist of what you all had out there.

Let me just have a couple quick parting comments if I could, before I turn it back to Dr. Castellanos to finish up.

One, thank you again for all being here. And I think I'll echo what Leslie Norwalk said earlier. That this is the Practicing Physicians Advisory Council and your counsel to us is enormously helpful. In that regard, much of the discussion today, if there was any one single topic, that we talked a lot about it's physician payment, there's no question, and the SGR. But I think the key here and I want to reflect back a little bit on the letter that Dr. Castellanos shared with us from a colleague of his in Louisiana. And that is the unique nature that we have and the opportunity to move forward this year. Unlike previous years and discussions on these issues, this one you have the Agency, you have Congress and ultimately all the stakeholder community, the physicians and others, working together on this issue. Everyone I've talked to, there is no disagreement that there are some problems here in terms of payment for this system. You've heard that Dr. McClellan has echoed this as have many others. And so the fact that you have all three of those groups continuing to work together to understanding what the issues are and trying to find a better way to do physician payment is unique in this community and in this city. And I think that bodes well for us to try to find an appropriate solution as we move forward. So as you read that letter, that's one of the things that sprung to mind that everybody continues to work on this. And I don't think, there's cause for concern, but not cause for alarm as we work forward and that's good to see where we are in that space, that's out there. The other thing I would just say is we say every meeting, but anything we can do as staff to improve the quality of the meeting and make the experience for all of you the members of the Council better, to help us and to get your points across would be useful. I would tell you this is Dr. Castellanos's third meeting as Chair of this committee, and from the staff standpoint I think he's done a tremendous job. From the aspect, and you would hopefully appreciate this, is that he constantly has his thumb in both Ken Simon's and my rib a lot on issues. [laughter] He's emailing us, he's calling us, he's being advocate for you, helping us work on agenda, helping us work on issues, making sure that we're aware of the concerns of the committee. And Dr. Castellanos, we appreciate that leadership and I just wanted the committee to know that he has really been I think a tremendous leader for this committee and thank you for that. [applause] I have nothing more, so turn it back to you for any closing remarks, and we'll be done.

Dr. Castellanos: Again, I want to thank all of you for being here and participating in this meeting. I think we've had a very productive meeting. The CMS staff has really worked hard in preparing this program and their presentation and sharing this with us and their concerns and specific requests for Council assistance. Our hope is that our recommendations will enhance the regulatory process and enable CMS to move forward with its mission and goals to provide quality care and services to the beneficiary and wide variety of customers and providers. I want to thank the CMS staff and contractors, who use their many skills, talents, and professionalism to make these Council meetings very successful. It surely requires a lot of work, coordination and communication, and we certainly, certainly appreciate it.

Our next meeting will be held on Monday, December 5th and with that, I think today's meeting is adjourned and thank you all.

One more question to the Council members, and I think Ken mentioned this briefly, earlier. The next meeting is December 5th and his question, the following meeting, do you want it held in February or March?

Dr. Simon: February 27th or March 6.

Dr. Castellanos: February 27 or March 6? Does anybody have any specific requests.

Mr. Kuhn: If you don't have your calendars with you, I guess you could email back to Ken.

Dr. Simon: That's right. We spoke about this last night at the dinner.

Dr. McAneny: The ASCO board meets on the February one, and so I would really appreciate it being the March 6th. One vote for March.

[chat]